## UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUST LITIGATION

IN RE: DOXYCYCLINE CASES

THIS DOCUMENT RELATES TO:

ALL DOXYCYCLINE DIRECT PURCHASER ACTIONS

AHOLD USA, INC.; CÉSAR CASTILLO, INC.; FWK HOLDINGS, L.L.C.; KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS, INC.; and ROCHESTER DRUG CO-OPERATIVE, INC.; on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

ACTAVIS HOLDCO U.S., INC.; HERITAGE PHARMACEUTICALS, INC.; MAYNE PHARMA USA, INC.; MYLAN INC.; MYLAN PHARMACEUTICALS INC.; PAR PHARMACEUTICAL, INC.; SUN PHARMACEUTICAL INDUSTRIES, INC.; and WEST-WARD PHARMACEUTICALS CORP.,

Defendants.

MDL 2724 16-MD-2724

HON. CYNTHIA M. RUFE

LEAD CASE: 16-DX-27240 DIRECT CASE: 16-DX-27241

JURY TRIAL DEMANDED

CONSOLIDATED DIRECT PURCHASER CLASS ACTION COMPLAINT

REDACTED PUBLIC VERSION CONTAINS INFORMATION REDACTED PURSUANT TO MDL 2724 PROTECTIVE ORDER

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#### I. INTRODUCTION

- 1. Plaintiffs Ahold USA, Inc., César Castillo, Inc., FWK Holdings, L.L.C., KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc., and Rochester Drug Co-Operative, Inc., on behalf of themselves and all others similarly situated, bring this Class Action Complaint on behalf of Class (defined below) of direct purchasers who purchased generic doxycycline hyclate ("Doxycycline")<sup>1</sup> directly from Defendants Actavis Holdco U.S., Inc., Heritage Pharmaceuticals, Inc., Mayne Pharma USA, Inc., Mylan Inc., Mylan Pharmaceuticals Inc., Par Pharmaceutical, Inc., Sun Pharmaceutical Industries, Inc., or West-Ward Pharmaceuticals Corp.
- 2. In the pharmaceutical industry, the entry of generic versions of branded drugs usually results in aggressive price competition, which in turn reduces prices for drug wholesalers, retail pharmacies, consumers, and third party payors. Defendants here, however, conspired to thwart the economic benefits of generic competition.
- 3. This is a civil action seeking treble damages arising out of the Defendants' unlawful scheme to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation of Doxycycline. As set forth below, Defendants' scheme violates Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants were not alone in subverting the operation of a competitive marketplace for generic pharmaceuticals. Defendants' anticompetitive conduct in the Doxycycline market is part of a larger conspiracy or series of conspiracies involving many generic pharmaceutical manufacturers and many generic pharmaceuticals.
- 4. Plaintiffs' allegations are based on personal knowledge of these matters relating to themselves and upon information and belief as to all other matters. Parts of Plaintiffs'

<sup>&</sup>lt;sup>1</sup> Regular release capsules (50 or 100mg) and tablets (100mg) (together, "Doxycycline Regular Release") or delayed release tablets (75, 100, and 150mg) ("Doxycycline DR"). Doxycycline Regular Release and Doxycycline DR are together referred to as "Doxycycline."

allegations are based on information made public during ongoing government investigations of Defendants and other generic pharmaceutical companies for alleged unlawful price-fixing and other conduct in the generic pharmaceutical industry.

- 5. Doxycycline is tetracycline antibiotic prescribed to patients for the treatment of a variety of bacterial infections, including acne, urinary tract infections, eye infections, Lyme disease, intestinal infections, sexually-transmitted diseases, and gum disease, among others.

  Doxycycline has been designated an essential medicine by the World Health Organization.<sup>2</sup>
- 6. Doxycycline has been available in the United States for many years and the market for Doxycycline is mature. Defendants dominate the market for Doxycycline. Doxycycline hyclate is available in capsule or tablet form and in different formulations, like regular release and delayed release ("DR").<sup>3</sup>
- 7. **Doxycycline Regular Release**: At least Defendants Actavis, Par, Sun, and West-Ward, as well as co-conspirators, engaged in an overarching anticompetitive scheme in at least the market for Doxycycline Regular Release to artificially inflate and stabilize prices through unlawful agreements. Defendants caused the price of these products to dramatically and inexplicably increase as much as higher than October 2012 prices, as alleged in Section V(B). The United States Government Accountability Office ("GAO") singled out Doxycycline

<sup>&</sup>lt;sup>2</sup> According to the World Health Organization: "Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford." World Health Organization Website, Essential medicines, *available at* <a href="http://www.who.int/topics/essential\_medicines/en/">http://www.who.int/topics/essential\_medicines/en/</a>.

<sup>&</sup>lt;sup>3</sup> According to package inserts, both formulations of doxycycline hyclate can be used to treat the same conditions.

Regular Release as an example of a generic pharmaceutical that "experienced an extraordinary price increase." This increase was the consequence of an agreement among the Defendants to increase pricing and restrain competition for the sale of Doxycycline in the United States.

- 8. *Doxycycline DR*: At least Defendants Heritage, Mayne, and Mylan, as well as coconspirators, engaged in an overarching anticompetitive scheme to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation of at least Doxycycline DR through unlawful agreements. The scheme caused prices of Doxycycline to be set or maintained above competitive levels. Evidence unearthed in government investigations directly shows Defendants Heritage, Mayne, and Mylan's involvement in the Doxycycline scheme, as alleged in Sections V(B) and (C).
- 9. Defendants orchestrated their collusion concerning Doxycycline through secret communications and meetings, both in private and at public events, such as trade association meetings held by the Generic Pharmaceutical Association ("GPhA") (now called the Association for Accessible Medicines),<sup>5</sup> the Healthcare Distribution Management Association ("HDMA") (now called the Healthcare Distribution Alliance), the Minnesota Multistate Contracting Alliance for Pharmacy ("MMCAP"), the National Association of Chain Drug Stores ("NACDS"), Efficient Collaborative Retail Marketing ("ECRM"), and the National Pharmacy Forum ("NPF"), among others.
- 10. Defendants' and other generic pharmaceutical manufacturers' conduct has resulted in extensive scrutiny by federal and state regulators, including by the Antitrust Division

<sup>&</sup>lt;sup>4</sup> GAO Report to Congressional Requesters, *Generic Drugs Under Medicare* (Aug. 2016), *available at* http://www.gao.gov/assets/680/679055.pdf.

<sup>&</sup>lt;sup>5</sup> See Russell Redman, New name for Generic Pharmaceutical Association, CHAIN DRUG REVIEW (Feb. 14, 2017), available at <a href="http://www.chaindrugreview.com/new-name-for-generic-pharmaceutical-association/">http://www.chaindrugreview.com/new-name-for-generic-pharmaceutical-association/</a>.

of the United States Department of Justice ("DOJ"), the United States Senate, the United States House of Representatives, and at least 45 attorneys general from 44 states and the District of Columbia (the "State AGs"). The DOJ empaneled a federal grand jury in this District, which has issued subpoenas relating to price-fixing and other anticompetitive conduct in the generic pharmaceutical industry, including to at least Defendants Actavis, Mayne, Mylan, Par, and Sun. As discussed below, generic doxycycline hyclate is known to be a focus of these investigations, which have resulted in criminal guilty pleas.

- 11. The DOJ's and State AGs' investigations followed a congressional hearing and investigation prompted by the National Community Pharmacists Association's ("NCPA")

  January 2014 correspondence to the United States Senate Health Education Labor and Pensions ("HELP") Committee and the United States House Energy and Commerce Committee requesting hearings on significant spikes in generic pharmaceutical pricing. The NCPA's news release reported price hikes on essential generic pharmaceuticals exceeding 1,000% in some instances, according to its survey of over a thousand community pharmacists, resulting in some patients being forced to leave their prescriptions at the pharmacy counter due to increased copays, and forcing more seniors into Medicare's coverage gap (or "donut hole") where they must pay far higher out-of-pocket costs.
- 12. On December 12 and 13, 2016, the DOJ filed its first criminal charges against Jeffrey Glazer and Jason Malek in their capacities as former executives of Defendant Heritage. See United States of America v. Jeffrey A. Glazer, No. 2:16-cr-00506-RBS (E.D. Pa.); United States of America v. Jason T. Malek, No. 2:16-cr-00508-RBS (E.D. Pa.). The DOJ alleged that

<sup>&</sup>lt;sup>6</sup> News Release, Generic Drug Price Spikes Demand Congressional Hearing, Pharmacists Say (Jan. 8, 2014), available at <a href="http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say">http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say</a>.

both Glazer and Malek conspired with others, including Defendants here, "to allocate customers, rig bids, and fix and maintain prices of doxycycline hyclate" and generic glyburide sold in the United States. Each was charged with two felony counts under the Sherman Act, 15 U.S.C. § 1.

13. On January 9, 2017, Glazer and Malek pled guilty to felony charges that they conspired with competitors to manipulate prices and allocate customers for doxycycline. Glazer admitted that:

[He] participated in a conspiracy with other persons and entities engaged in the production and sale of generic pharmaceutical products including Doxycycline Hyclate, the primary purpose of which was to allocate customers, rig bids and fix and maintain prices of Doxycycline Hyclate sold in the United States in furtherance of the conspiracy.

Defendant and his co-conspirators, including individuals that the defendant supervised at his company and those he reported to at his company's parent, engaged in discussions and attended meetings with the co-conspirators involved in the production and sale of Doxycycline Hyclate. During such discussions and meetings, agreements were reached to allocate customers, rig bids and fix and maintain the prices of Doxycycline Hyclate sold in the United States.<sup>7</sup>

- 14. Malek admitted substantially the same facts. 8 Glazer and Malek continue to cooperate with the DOJ's ongoing investigation as they await sentencing.
- 15. The DOJ has publicly acknowledged that its investigation overlaps with MDL 2724 and Doxycycline specifically. For example, the DOJ filed a motion for a stay of discovery in MDL 2724 noting that:

Evidence uncovered during the criminal investigation implicates other companies and individuals (including a significant number of the Defendants here) in collusion with respect to doxycycline

<sup>&</sup>lt;sup>7</sup> Tr. of Plea Hearing at 19:16-20:4, *United States v. Glazer*, No. 16-cr-506, ECF 24 (E.D. Pa. Jan. 9, 2017); *see also id.* at 22:4-11 (admitting facts).

<sup>&</sup>lt;sup>8</sup> Tr. of Plea Hearing at 19:12-20:1, *United States v. Malek*, No. 16-cr-508, ECF 24 (E.D. Pa. Jan. 9, 2017); *see also id.* at 21:23-22:6 (admitting facts).

- hyclate, glyburide, and other drugs (including a significant number of the drugs at issue here).<sup>9</sup>
- Soon after the DOJ filed criminal charges, 20 state attorneys general led by the State of Connecticut also sued generic manufacturers Aurobindo, Citron, Heritage, and Teva, as well as Mayne and Mylan for bid rigging, price-fixing and market and customer allocation in connection with their sale of Doxycycline DR and generic glyburide in the United States. On March 1, 2017, the complaint in the State AGs' action was amended to, *inter alia*, add claims of an additional 20 state attorneys general, bringing the total number of state AGs prosecuting the action to 40. Glazer and Malek entered into settlement agreements with the attorneys general on March 16, 2017. Commenting on the scope of its current antitrust investigation, the Connecticut Attorney General ("CTAG") George Jepsen stated that "[t]he issues we're investigating go *way beyond* the two drugs and six companies. *Way beyond...We're learning new things every day.*" On July 17, 2017, 5 additional attorneys general joined the action by filing a nearly identical complaint and a notice of related case.<sup>12</sup>
- 17. As noted above, the State AGs' and DOJ's investigations are ongoing. Just last week, Pfizer Inc. reported in an SEC filing dated August 10, 2017 that:

As of July 2017, the U.S. Department of Justice's Antitrust Division is investigating our Greenstone generics business. We believe this is related to an ongoing antitrust investigation of the generic

<sup>&</sup>lt;sup>9</sup> See Intervenor United States' Motion to Stay Discovery, *In re: Generic Pharm. Pricing Antitrust Litig.*, MDL No. 2724, ECF 279 (E.D. Pa. May 1, 2017).

<sup>&</sup>lt;sup>10</sup> John Kennedy, *Ex-Heritage Execs to Help States Probe Drug Price-Fixing*, LAW360 (May 24, 2017), *available at* <a href="https://www.law360.com/competition/articles/927899/ex-heritage-execs-to-help-states-probe-drug-price-fixing?nl\_pk=eb0b62b3-08e3-46ed-ac8a-7ab5fa616c07&utm\_source=newsletter&utm\_medium=email&utm\_campaign=competition.">https://www.law360.com/competition/articles/927899/ex-heritage-execs-to-help-states-probe-drug-price-fixing?nl\_pk=eb0b62b3-08e3-46ed-ac8a-7ab5fa616c07&utm\_source=newsletter&utm\_medium=email&utm\_campaign=competition.

<sup>&</sup>lt;sup>11</sup> Liz Szabo, et al., *How Martinis, Steaks, and a Golf Round Raised Your Prescription Drug Prices*, THE DAILY BEAST (Dec. 21, 2016), *available at* <a href="http://thebea.st/2haV9xg">http://thebea.st/2haV9xg</a> (emphasis added).

<sup>&</sup>lt;sup>12</sup> Arkansas v. Aurobindo Pharma USA, Inc., No. 17-cv-1180 (filed in D. Conn.).

- pharmaceutical industry. The government has been obtaining information from Greenstone.
- 18. As a result of Defendants' scheme to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation of Doxycycline, direct purchasers paid, and continue to pay, supracompetitive prices for Doxycycline.
- 19. Plaintiffs, on behalf of themselves and members of direct purchaser class, seek damages caused by Defendants' and co-conspirators' violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.

#### II. JURISDICTION AND VENUE

- 20. This Court has jurisdiction over the subject matter of this action as it arises under Section 1 of the Sherman Act, 15 U.S.C. § 1, and Section 4 of the Clayton Act, 15 U.S.C. § 15. Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).
- 21. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391(b), (c), and (d), because during the Class Period Defendants transacted business throughout the United States, including in this District, Defendants resided, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.
- 22. During the Class Period, Defendants sold and distributed generic pharmaceuticals in a continuous and uninterrupted flow of interstate commerce, which included sales of Doxycycline in the United States, including in this District. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.
- 23. This Court has personal jurisdiction over each Defendant because, *inter alia*, each Defendant: (a) transacted business throughout the United States, including in this District;

(b) participated in the selling and distribution of Doxycycline throughout the United States, including in this District; (c) had and maintained substantial contacts within the United States, including in this District; and/or (d) was engaged in an unlawful conspiracy to inflate prices for Doxycycline that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

#### III. PARTIES

#### A. Plaintiffs

- 24. Plaintiff Ahold USA, Inc. ("Ahold") is a Maryland corporation with its principal places of business in Quincy, Massachusetts and Carlisle, Pennsylvania. During the Class Period, Ahold purchased Doxycycline directly from one or more Defendants. As a result of Defendants' antitrust conspiracy, Ahold paid supracompetitive prices for its Doxycycline purchases and was injured by the illegal conduct alleged herein.
- 25. Plaintiff César Castillo, Inc. ("CCI") is a Puerto Rico corporation with its principal place of business in Rio Piedras, Puerto Rico. During the Class Period, CCI purchased Doxycycline directly from one or more Defendants. As a result of Defendants' antitrust conspiracy, CCI paid supracompetitive prices for its Doxycycline purchases and was injured by the illegal conduct alleged herein.
- 26. Plaintiff FWK Holdings, LLC ("FWK") is an Illinois corporation with its principal place of business in Glen Ellyn, Illinois. FWK is the assignee of antitrust claims possessed by Frank W. Kerr Company ("Kerr") and brings this action as successor-in-interest to Kerr's claims arising from its purchase of Doxycycline directly from one or more of the Defendants during the Class Period. As a result of Defendants' antitrust conspiracy, FWK, through assignor Kerr, paid supracompetitive prices for its Doxycycline purchases and was injured by the illegal conduct alleged herein.

- 27. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a New York corporation with its principal place of business in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. During the Class Period, KPH directly purchased Doxycycline from one or more of the Defendants. As a result of Defendants' antitrust conspiracy, KPH paid supracompetitive prices for its Doxycycline purchases, and KPH was injured by the illegal conduct alleged herein.
- 28. Plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a New York corporation with its principal place of business in Rochester, New York. During the Class Period, RDC purchased Doxycycline directly from one or more of the Defendants at artificially and unlawfully inflated prices. As a result of Defendants' antitrust conspiracy, RDC paid supracompetitive prices for its Doxycycline purchases, and RDC was injured by the illegal conduct alleged herein.

#### B. Defendants

- 29. Defendant Actavis Holdco U.S., Inc. ("Actavis") is a Delaware corporation with its principal place of business in Parsippany, New Jersey. In August 2016, Teva Pharmaceuticals U.S., Inc. acquired Allergan plc's generics business (including Actavis). During the Class Period, Actavis sold Doxycycline to purchasers in this District and throughout the United States.
- 30. Defendant Heritage Pharmaceuticals, Inc. ("Heritage") is a Delaware corporation with its principal place of business in Eatontown, New Jersey. Heritage is a subsidiary of Emcure Pharmaceuticals Limited, an Indian pharmaceutical company. During the Class Period, Heritage sold Doxycycline to purchasers in this District and throughout the United States.
- 31. Defendant Mayne Pharma USA, Inc. ("Mayne") is a Delaware corporation with its principal place of business in Raleigh, North Carolina. During the Class Period, Mayne sold Doxycycline to purchasers in this District and throughout the United States.

- 32. Defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business in Canonsburg, Pennsylvania.
- 33. Defendant Mylan Pharmaceuticals Inc. is a West Virginia corporation with its principal place of business in Morgantown, West Virginia.
- 34. Mylan Inc. and Mylan Pharmaceuticals Inc. are wholly-owned subsidiaries of Mylan N.V., a Dutch pharmaceutical company. In this complaint, Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. are together referred to as "Mylan." During the Class Period, Mylan sold Doxycycline to purchasers in this District and throughout the United States.
- 35. Defendant Par Pharmaceutical Inc. ("Par") is a subsidiary of Endo International plc ("Endo"), an Irish pharmaceutical company. In September 2015, Endo completed an acquisition of Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par, from a private investment firm for about \$8 billion in cash and stock. At that time Endo created a combined U.S. Generics segment that included Par, and Endo's subsidiary Qualitest, naming the segment Par Pharmaceutical, Inc. Further, in August 2014, Endo acquired DAVA Pharmaceuticals, Inc. ("DAVA") and folded DAVA into Par. In this complaint, Endo, DAVA, and Par will be referred to as "Par." During the Class Period, Par sold Doxycycline to purchasers in this District and throughout the United States.
- 36. Defendant Sun Pharmaceutical Industries, Inc. ("Sun") is a Michigan corporation with its principal place of business in Cranbury, New Jersey. In late 2012, Sun acquired URL Pharma, Inc. ("URL") with its principal place of business in Philadelphia, PA. URL is a whollyowned subsidiary of Sun. URL as a group includes five wholly-owned subsidiaries, including Mutual Pharmaceutical Company, Inc. During the Class Period, Sun sold Doxycycline to purchasers in this District and throughout the United States.

- 37. Defendant West-Ward Pharmaceuticals Corporation ("West-Ward") is a Delaware corporation with its principal place of business in Eatontown, New Jersey. During the Class Period, West-Ward sold Doxycycline to purchasers in this District and throughout the United States.
- 38. Defendants and their officers, agents, employees, or representatives have engaged in the conduct alleged in this Complaint while actively involved in the management of Defendants' business and affairs.

## C. Co-Conspirators

- 39. Various other persons, firms, entities, and corporations, not named as defendants in this Complaint, have participated as co-conspirators with Defendants in the violations alleged herein, and have aided, abetted, and performed acts and made statements in furtherance of the conspiracy.
- 40. The true names and capacities of additional co-conspirators, whether individual, corporate, associate, or representative, are presently unknown to Plaintiffs. Plaintiffs may amend this Complaint to allege the true names and capacities of additional co-conspirators as they are discovered.
- 41. At all relevant times, other persons, firms, and corporations, referred to herein as "co-conspirators," the identities of which are presently unknown, have willingly conspired with Defendants in their unlawful scheme as described herein.
- 42. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

43. The wrongful acts alleged to have been done by any one Defendant or coconspirator were authorized, ordered, or done by its directors, officers, managers, agents, employees, or representatives while actively engaged in the management, direction, or control of such Defendant's or co-conspirator's affairs.

#### IV. INTERSTATE TRADE AND COMMERCE

- 44. Defendants are the leading manufacturers and suppliers of Doxycycline sold in the United States.
- 45. Doxycycline is produced by or on behalf of Defendants or their affiliates in the United States or overseas.
- 46. During the Class Period, Defendants, directly or through one or more of their affiliates, sold Doxycycline throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.
- 47. The activities of Defendants and their co-conspirators were within the flow of, intended to, and had a substantial effect on interstate commerce in the United States.
- 48. Defendants' and their co-conspirators' conduct, including the marketing and sale of Doxycycline, took place within, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.
- 49. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce in that Defendants deprived Plaintiffs of the benefits of free and open competition in the purchase of Doxycycline within the United States.
- 50. Defendants' agreement to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation of Doxycycline, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Doxycycline prices, were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States.

#### V. FACTUAL ALLEGATIONS

- A. The Generic Drug Market Is a Commodities Market, Where Competition Historically Has Been Keen.
  - 1. Generic drugs should lead to lower prices.
- 51. Generic drugs provide a lower-cost but bioequivalent alternative to brand drugs. Before any generic drug can be marketed, the Food and Drug Administration (the "FDA") requires rigorous testing to ensure it has the same strength, quality, safety, and performance as the brand. By law, generics must have the same amount of active ingredient and must be "therapeutically equivalent" to the brand, meaning they must meet exacting bioequivalence testing specifications so patients can expect "equal effect and no difference when [generics are] substituted for the brand name product." <sup>13</sup>
- 52. To encourage the production and sale of generic drugs, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") simplified the regulatory hurdles that generic pharmaceutical manufacturers have to clear before marketing and selling generic pharmaceuticals. Instead of filing a lengthy and costly New Drug Application, the Hatch-Waxman Act allows generic pharmaceutical manufacturers to obtain FDA approval in an expedited fashion.
- 53. To obtain marketing approval for a generic pharmaceutical, an Abbreviated New Drug Application ("ANDA") must be filed with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs; "abbreviated" because so long as the ANDA includes data showing bioequivalence to the brand, the ANDA sponsor can reference efficacy data supporting approval of the brand (described in the regulations as the "Reference Listed Drug" or "RLD" for

<sup>&</sup>lt;sup>13</sup> FDA, *Drugs@FDA Glossary of Terms*, available at <a href="http://www.fda.gov/Drugs/">http://www.fda.gov/Drugs/</a> InformationOnDrugs/ucm079436.htm#G.

short) instead of repeating all the same clinical trials. Upon the FDA's determination that bioequivalence to the brand has been established, the ANDA will be approved and may be marketed in the United States as substitutable with the RLD.

- 54. Although equivalent from a safety and efficacy standpoint, generic versions of brand name drugs are priced significantly below their brand counterparts, and because of this, they rapidly gain market share from the brand beginning immediately following launch. Indeed, in every state, pharmacists are permitted (and in many states required) to substitute a generic product for a brand product barring a note from a doctor that the brand product must be dispensed as written.
- 55. It is well established in economic literature that competition by generic products results in lower prices for drug purchasers. In the period before generic entry, a brand drug commands 100% of the market share for that drug and the brand manufacturer can set the price free from competitive market forces. But once the first lower-priced generic enters, a brand drug rapidly loses sales due to automatic pharmacy counter substitution, and generics capture as much as 80% of the market or more within months of launch. And as more generics become available, generic prices only decline further due to competition among generics. These cost reductions to drug purchasers were the very legislative purpose behind the abbreviated regulatory pathway for generic approval under the Hatch Waxman Act.
- 56. Generic competition, under lawful and competitive circumstances, reduces drug costs by driving down the prices of both generic versions of the brand drug and often the brand drug itself, and every year generic drugs result in hundreds of billions of dollars in savings to consumers, insurers, and other drug purchasers.

- 57. A Federal Trade Commission study found that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices." A mature generic market, such as the market for Doxycycline, has several generic competitors. Because each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers. Over time, generics' pricing nears the generic manufacturers' marginal costs.
- 58. Generic competition usually enables purchasers to purchase generic versions of the brand drug at a substantially lower price than the brand drug. Generic competition to a single blockbuster brand drug can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic drugs saved the United States healthcare system \$1.68 trillion between 2005 and 2014.<sup>16</sup>

<sup>&</sup>lt;sup>14</sup> Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, at 8 (Jan. 2010), *available at* <a href="https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff">https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff</a>.

<sup>15</sup> See, e.g., Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, at 17 (Aug. 2011) ("[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price."), available at <a href="https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission">https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission</a>; U.S. Cong. Budget Office, How Increased Competition from Generic Drugs Has Affected Proceed and Returns in the Pharmaceutical Industry (July 1998), available at <a href="https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf">https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf</a>.

<sup>&</sup>lt;sup>16</sup> GPhA, GENERIC DRUG SAVINGS IN THE U.S. (7th ed. 2015) at 1, *available at* http://www.gphaonline.org/media/wysiwyg/PDF/GPhA Savings Report 2015.pdf.

- 2. Prescription drug prices in the United States are governed by institutional safeguards, which are intended to keep drug prices competitive.
- 59. Ordinarily, the price for a consumer product is set by the retailer based on the amount the typical consumer is willing to pay. But because of the unique features of the prescription drug marketplace, prescription drug pricing for most consumers is not determined between the retailer and the consumer. Rather, because most consumers' prescription drug purchases are reimbursed by public or private health plans, consumer pricing for prescription drugs is determined by reimbursement agreements between these prescription drug payers, *i.e.*, health plans and their prescription benefit managers, and the pharmacies that dispense drugs to the payers' insured customers.
- 60. Generic manufacturers typically report a Wholesale Acquisition Cost ("WAC") for their drugs. WAC prices represent the manufacturer's benchmark or reported list price. The WAC typically functions as the manufacturer's list or benchmark price in sales to wholesalers or other direct purchasers and typically does not include discounts that may be provided, *e.g.*, for volume sales. Manufacturers generally provide their WACs to purchasers or report them to publishers that compile that information for the market.<sup>17</sup>
- 61. Generic drug manufacturers may charge different amounts for an equally interchangeable, *i.e.*, therapeutically equivalent, multisource drug. But manufacturers are usually constrained in their ability to price generic drugs by the Maximum Allowable Cost ("MAC").<sup>18</sup>

<sup>&</sup>lt;sup>17</sup> At one time, payors relied on cost-based pricing metrics to reimburse pharmacies that dispensed drugs to their insured customers, paying the dispensing pharmacies an amount based on the manufacturer's list price for the drug, plus a small mark-up or dispensing fee. Over time, however, it was learned that the list price for most generic drugs published by their manufacturers was substantially higher than the actual cost incurred by pharmacies to acquire the drugs.

<sup>&</sup>lt;sup>18</sup> To define therapeutic categories, MAC pricing typically relies on the FDA's Orange Book, which lists approved prescription drugs and their therapeutic equivalents. An "A"-rated

MAC is a contractually based payment model that, in the private sector, is commonly established by a pharmacy benefits manager ("PBM"), who manages an insurance plan, and that is paid to the pharmacies within the plan's network.<sup>19</sup> A MAC price sets the upper limit that a pharmacy will be paid by the PBM for procuring and dispensing a particular generic medication.

- 62. While PBMs usually do not disclose publicly which drugs they subject to MAC pricing, what the MAC price is, or what factors they apply to set MAC prices, it is believed that PBMs rely on a wide-variety of market-wide pricing information or plan-specific data.<sup>20</sup> In recent years, 79% of employer prescription drug plans and 45 state Medicaid programs have been using MAC prices to control the cost of generic drugs.<sup>21</sup> MAC prices give pharmacies an incentive to procure and dispense the lowest-priced drug product available for a particular multisource drug. If a generic drug is subject to MAC pricing, a pharmacy purchasing a higher-priced generic product will make less profit or potentially even lose money when it dispenses a higher-priced product.<sup>22</sup>
- 63. MAC pricing is neither uniform, nor transparent and may be subject to frequent changes. So whether a generic manufacturer's products are even subject to MAC pricing or how

drug is one that the FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products. *See* U.S. FDA Website, Orange Book Preface, *available at* <a href="https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#tecode">https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#tecode</a>.

<sup>&</sup>lt;sup>19</sup> Academy of Managed Care Pharmacy, *Where We Stand, Maximum Allowable Cost* (MAC) Pricing (Dec. 2013), available at <a href="www.amcp.org/Sec.aspx?id=9287">www.amcp.org/Sec.aspx?id=9287</a>. For the purposes of this complaint, MAC prices refer solely to prices that limit a pharmacy's reimbursement for generic drugs, not the amounts PBMs charge to the insurance plans, which may also be referred to as a MAC price. See National Community Pharmacists Association, *The Need for Legislation Regarding "Maximum Allowable Cost"* (MAC) Reimbursement, available at <a href="http://www.ncpa.co/pdf/leg/mac-one-pager.pdf">http://www.ncpa.co/pdf/leg/mac-one-pager.pdf</a>.

<sup>&</sup>lt;sup>20</sup> *Id*.

<sup>&</sup>lt;sup>21</sup> Express Scripts, *MAC Pricing Incents More Affordable Rx* (Feb. 24, 2016), *available at* <a href="http://lab.express-scripts.com/lab/insights/drug-options/mac-pricing-incents-more-affordable-rx">http://lab.express-scripts.com/lab/insights/drug-options/mac-pricing-incents-more-affordable-rx</a>.

<sup>&</sup>lt;sup>22</sup> See supra Academy of Managed Care Pharmacy article.

that MAC pricing is set for any particular generic drug is not easy for the manufacturers to decipher. PBMs typically exercise control over the selection of generic medications that will be subjected to MAC pricing, and they fiercely guard the secrecy of their MAC price lists.<sup>23</sup> Industry groups, like the Academy of Managed Care Pharmacy, actively oppose government regulation of MAC pricing and any efforts to disclose MAC prices or the method of calculating them.<sup>24</sup>

- 64. By setting a ceiling for reimbursement of any particular generic drug at the pharmacy level, MAC prices indirectly affect the price at which generic drug manufacturers may sell their products to direct purchasers. Because many generic drugs are subject to MAC pricing, generic drug manufacturers have an incentive to price their generic drug products competitively to maintain demand by pharmacies.
- own when its competitors do not. A unilateral price increase in a competitive generic drug market that is subject to MAC pricing is likely to send buyers to a lower-price alternative. MAC pricing has little effect if generic drug manufacturers collectively increase their prices for a multi-source drug. First, PBMs generally permit pharmacies—who may be contractually obligated to dispense an unprofitable prescription—to challenge MAC prices under a MAC appeals process.<sup>25</sup> If the price of a generic drug has been increased by the majority of generic drug manufacturers, then these MAC appeals may be successful in getting the PBM to increase the MAC price allowed. Second, PBMs typically have a policy of revising MAC prices under

<sup>&</sup>lt;sup>23</sup> See supra National Community Pharmacists Association article.

<sup>&</sup>lt;sup>24</sup> See supra Academy of Managed Care Pharmacy article.

<sup>&</sup>lt;sup>25</sup> *Id*.

certain contingencies.<sup>26</sup> One large PBM, Express Scripts, for example, states that its MAC price list is frequently updated to reflect "the current market dynamics."<sup>27</sup>

66. MAC pricing provides yet another reason that Defendants' stark increases in the price of Doxycycline are indicative of coordinated pricing activity. Knowing that they hold an overwhelming majority share of the market for Doxycycline, Defendants had the capacity to dictate the market price and to influence the MAC prices set by PBMs, but only if they acted collectively. Absent collusion, individual Defendants could not have increased their prices to the high levels they did (or maintain high prices in the face of a significantly lower competitor price) without incurring the loss of a significant volume of sales.

## B. Defendants Conspired to, Among Other Things, Fix Doxycycline Prices.

- 67. On January 9, 2017, Glazer and Malek entered guilty pleas admitting that they have "participated in a conspiracy with other persons and entities engaged in the production and sale of generic pharmaceutical products, including Doxycycline Hyclate, the primary purposes of which was to allocate customer, rig bids and fix and maintain prices of Doxycycline Hyclate sold in the United States in furtherance of the conspiracy." Glazer and Malek further admitted that they "attended meetings with the co-conspirators involved in the production and sale of Doxycycline Hyclate" and that during these meetings "agreements were reached to allocate customers, rig bids and fix and maintain the prices of Doxycycline Hyclate sold in the United States."
- 68. The DOJ's grand jury, which is empaneled in this District, is known to have subpoenaed, among others, Defendants Actavis, Heritage, Mayne, Mylan, and Sun.

 $<sup>^{26}</sup>$  *Id*.

<sup>&</sup>lt;sup>27</sup> See supra Express Scripts article.

69. The State AGs have also filed suit stating:

In July 2014, the State of Connecticut initiated a non-public investigation into suspicious price increases for certain generic pharmaceuticals. The information developed through that investigation, which is still ongoing, uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States. In this initial civil action, the Plaintiff States charge the Defendants with entering into contracts, combinations and conspiracies that had the effect of unreasonably restraining trade, artificially inflating and maintaining prices and reducing competition in the markets for Doxycycline Hyclate Delayed Release ("Doxy DR") and Glyburide in the United States.<sup>28</sup>

70. The DOJ's and State AGs' investigations are ongoing.

## 1. Doxycycline Regular Release

- a. Defendants' dominance over Doxycycline Regular Release sales permitted them to fix prices, rig bids, and engage in market and customer allocation, and their abrupt price increases are otherwise inexplicable.
- 71. The market for Doxycycline Regular Release is mature, as generic versions have been on the market for years. In 2013 alone, Defendants' total revenue from direct sales of Doxycycline Regular Release was approximately \_\_\_\_\_\_\_. This compares to only approximately \_\_\_\_\_\_\_ in 2011, a year before the price-fixing conspiracy.

<sup>&</sup>lt;sup>28</sup> Amended Complaint (Public Version) ¶1, *Connecticut v. Aurobindo Pharma USA*, *Inc.*, No. 16-cv-2056, ECF 168 (D. Conn.), *available at* <a href="http://www.ct.gov/ag/lib/ag/press">http://www.ct.gov/ag/lib/ag/press</a> releases/2016/20161215 gdms complain.pdf.

<sup>&</sup>lt;sup>29</sup> Revenue, unit sales, and effective prices are obtained from QuintilesIMS Inc. ("IMS Health"). IMS Health is the largest vendor of physicians' prescribing data in the United States and is widely relied upon in the pharmaceutical industry and elsewhere. As used in this complaint, "effective prices" represent actual transaction prices, as reported by IMS Health. Plaintiffs calculate Defendants' effective prices based on IMS Health's National Sales Perspectives ("NSP") data, which "captures 100% of the total U.S. pharmaceutical market, measuring sales at actual transaction prices[.]" IMS Institute for Healthcare Informatics, HSRN Data Brief: National Sales Perspectives, at 1, *available at* https://www.imshealth.com/files/web/IMSH%20Institute/NSP Data Brief-.pdf.

- 72. A mature generic market, such as the market for Doxycycline, has several generic competitors. As noted above, because each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers. In a market free from collusive activity, over time, generics' pricing would naturally near (and stay near) the generic manufacturers' marginal costs.
- 73. At all times relevant for this lawsuit, there have been multiple manufacturers of Doxycycline Regular Release. Under accepted economic principles of competition, when there are multiple generics prices should remain at very competitive, historic levels, and would not increase as they did here absent anticompetitive conduct. Drastic increases in generic Doxycycline Regular Release prices are themselves suggestive of Defendants' collective dominance: if they did not already dominate the market, Defendants' pricing excesses would be disciplined because they would lose market share to non-colluding competitors.
  - b. Defendants' collective market dominance permitted them to collude.
- 74. During the Class Period, Defendants Actavis, Par, Sun, and West-Ward dominated Doxycycline Regular Release sales with about an share.<sup>30</sup> Likewise, before the Class Period, from May 2010 through October 2012, their sales made up about roughly of all United States direct purchases of generic Doxycycline Regular Release.

Effective prices are calculated to multiple decimals. For ease of reference, prices in this complaint are rounded to the nearest cent. However, percentage increases are calculated based on the more precisely calculated price.

<sup>&</sup>lt;sup>30</sup> Market share is calculated in this complaint by reference to IMS unit sales data.

90.

- d. As part of the conspiracy, Defendants increased their WAC benchmarks exorbitantly within weeks of each other.
- 91. Although MAC pricing has been implemented to discourage unilateral price increases of generic drugs by setting an upper limit, an individual manufacturer's WAC increase may influence the actual prices paid by direct purchasers. This is the case here, where Defendants Actavis, Sun, and West-Ward dominate Doxycycline Regular Release sales. Even though their WAC prices changes represented about a twenty fold increase from previous WACs, Defendants raised Doxycycline Regular Release WACs on the 50 mg capsules to identical benchmark prices over a two-week period:<sup>31</sup>

Product	Defendant	NDC	Old WAC	New WAC	Date of Increase	Percentage increase
50 mg cap, 50 ct.	West- Ward	00143-3141- 50	\$0.09	\$1.80	21-Jan-13	1,903%
50 mg cap, 50 ct.	Actavis	00591-5535- 50	\$0.10	\$1.80	1-Feb-13	1,782%
50 mg cap, 50 ct.	Sun	53489-0118- 02	\$0.09	\$1.80	5-Feb-13	1,953%
50 mg cap, 500 ct.	Sun	53489-0118- 05	\$0.08	\$1.80	5-Feb-13	2,181%

92. In the same two-week period, Defendants also increased their WACs on their 100 mg capsules and 100 mg tablets by as much as 7,844%:

<sup>&</sup>lt;sup>31</sup> For ease of reference, WAC prices are rounded to the nearest cent, but the percentage increases are calculated on the actual reported WACs.

Product	Defendant	NDC	Old WAC	New WAC	Date of Increase	Percentage increase
100 mg cap, 50 ct.	West- Ward	00143-3142- 50	\$0.10	\$4.43	21-Jan-13	4,326%
100 mg cap, 50 ct.	Actavis	00591-5440- 50	\$0.10	\$2.74	1-Feb-13	2,515%
100 mg cap, 50 ct.	Sun	53489-0119- 02	\$0.10	\$4.92	5-Feb-13	4,847%

Product	Defendant	NDC	Old WAC	New WAC	Date of Increase	Percentage increase
100 mg cap, 500 ct.	West- Ward	00143-3142- 05	\$0.10	\$4.43	21-Jan-13	4,370%
100 mg cap, 500 ct.	Actavis	00591-5440- 05	\$0.10	\$2.74	1-Feb-13	2,663%
100 mg cap, 500 ct.	Sun	53489-0119- 05	\$0.06	\$4.92	5-Feb-13	7,844%

Product	Defendant	NDC	Old WAC	New WAC	Date of Increase	Percentage increase
100 mg tab, 50 ct.	Actavis	00591-5553- 50	\$0.10	\$2.74	1-Feb-13	2,515%
100 mg tab, 50 ct.	Sun	53489-0120- 02	\$0.09	\$4.92	5-Feb-13	5,631%

Product	Defendant	NDC	Old WAC	New WAC	Date of Increase	Percentage increase
100 mg tab, 500 ct.	Actavis	00591-5553- 05	\$0.10	\$2.74	1-Feb-13	2,663%
100 mg tab, 500 ct.	Sun	53489-0120- 05	\$0.08	\$4.92	5-Feb-13	6,268%

- e. Whatever shortages or other market changes may have occurred during the Class Period, they alone cannot have caused the extraordinary price increases.
- 93. Federal law requires mandatory drug shortage reporting for drug manufacturers.<sup>32</sup> The FDA originally reported a shortage of some forms of doxycycline hyclate on January 18, 2013, and continued to report in mid-2013 shortage from some, but not all, manufacturers of some dosages and forms of doxycycline hyclate.<sup>33</sup> Some of the Doxycycline Regular Release products also appear on archived lists of the American Society of Health-System Pharmacists ("ASHP") Current Shortage Bulletins during the Class Period. However, these statements are not inconsistent with Defendants' price collusion.
  - i. Reported "shortages" do not correlate with reduced sales.
- 94. ASHP did not report any shortages of Actavis' 100 mg tablets, but in December 2012, May 2013, July 2013, January 2014, March 2014, June 2014, and July 2014, it reported shortages of Actavis' 50 mg and 100 mg capsules.<sup>34</sup> By January 14, 2015, ASHP described the shortage "resolved,"<sup>35</sup> and on May 18, 2015, it listed Actavis' 50 mg and 100 mg capsules as "available."<sup>36</sup> Actavis communicated with ASHP that the reason for its purported capsule shortages was "supply and demand."<sup>37</sup> Despite its reported capsule "shortages," Actavis' 2013 capsule sales increased.

 $<sup>^{32}</sup>$  FDA Safety and Innovation Act of 2012, Pub. L. No. 112-144, §§ 1001-1008, 126 STAT. 995, 1099-1108.

<sup>&</sup>lt;sup>33</sup> CDC Health Advisory (June 12, 2013), *available at* https://emergency.cdc.gov/han/han00349.asp.

<sup>&</sup>lt;sup>34</sup> ASHP, Current Drug Shortage Bulletin: Doxycycline Capsules and Tablets ("Current Drug Shortage Bulletin") (December 10, 2012; May 20, 2013; July 10, 2013; January 15, 2014; March 6, 2014; June 23, 2014; and July 18, 2014).

<sup>&</sup>lt;sup>35</sup> ASHP, Current Drug Shortage Bulletin (January 14, 2015).

<sup>&</sup>lt;sup>36</sup> ASHP, Current Drug Shortage Bulletin (May 18, 2015).

<sup>&</sup>lt;sup>37</sup> ASHP, Current Drug Shortage Bulletin (July 18, 2014) n.8.

That sales increased during the purported shortage and decreased when drugs were available, undermines any claim that shortages caused Actavis' price increases.

95. In December 2012, May 2013, and July 2013, ASHP reported shortages of Sun's 50 mg and 100 mg capsules and 100 mg tablets.<sup>38</sup> By January 2014, all three products were listed as "available."<sup>39</sup> According to Sun (formerly Mutual), the shortages were the result of an unspecified "raw material shortage."<sup>40</sup> Archived ASHP lists indicate that Sun was the only manufacturer of Doxycycline tablets and capsules to make this claim. Despite its reported "shortages" in 2013,

That its sales volume increased during the purported shortage and decreased when its drugs became available, undermines any claim that shortages caused Sun's price increases.

96. ASHP reported shortages of West-Ward's 50 mg capsules and of certain bottle sizes of its 100 mg capsules and tablets in December 2012.<sup>41</sup> By May 2013, all three products were reported as "available" again, although West-Ward discontinued its 20 count bottle of 100 mg capsules.<sup>42</sup> Notably, ASHP reported that West-Ward "could not provide a reason for the

<sup>&</sup>lt;sup>38</sup> ASHP, Current Drug Shortage Bulletin (December 10, 2012; May 20, 2013; July 10, 2013).

<sup>&</sup>lt;sup>39</sup> ASHP, Current Drug Shortage Bulletin (January 15, 2014).

<sup>&</sup>lt;sup>40</sup> ASHP, Current Drug Shortage Bulletin (July 10, 2013), at n.4.

<sup>&</sup>lt;sup>41</sup> ASHP, Current Drug Shortage Bulletin (December 10, 2012).

<sup>&</sup>lt;sup>42</sup> ASHP, Current Drug Shortage Bulletin (May 20, 2013).



- ii. Defendants' exponential increases in revenue also support price collusion.
- 97. Revenue for Doxycycline Regular Release skyrocketed, a feat Defendants could not have accomplished absent collusion. Between 2012 and 2013, Defendant Sun's revenue increased ; Defendant Actavis' revenue increased ; and West-Ward's revenue increased .
- 98. Nor does any change in the marketplace explain the rising prices—before the Class Period, from 2010 to 2013, Defendants accounted for roughly of the direct sales of Doxycycline Regular Release. During the Class Period, Defendants Actavis, Par, Sun, and West-Ward maintained about of Doxycycline Regular Release sales.
  - f. Evidence unearthed in a related case corroborates Par's involvement in the conspiracy.
- 99. By April 2014, DAVA launched Doxycycline Regular Release pursuant to an exclusive supply and distribution agreement with Chartwell Therapeutics Licensing, LLC and Chartwell Pharmaceuticals, LLC ("Chartwell"). Around this time, Endo was in discussions with DAVA to acquire it, which it did in August 2014.
- 100. Following DAVA's acquisition by Endo, Chartwell and Endo sued each other in New York state court for alleged failures to comply with the terms of the supply and distribution agreement for Doxycycline.<sup>44</sup> Chartwell alleged that DAVA, DAVA's former President Aram

<sup>&</sup>lt;sup>43</sup> ASHP, Current Drug Shortage Bulletin (December 10, 2012).

<sup>&</sup>lt;sup>44</sup> See Dava Pharm., LLC v. Chartwell Therapeutics Licensing, LLC, Index No. 502775/15 (N.Y. Supreme Court, County of Kings).

Moezinia, and Endo (through its generics subsidiaries) were refusing to take delivery of Doxycycline shipments from Chartwell despite the fact that there was demand for Doxycycline in the market. Because Endo (through its generics subsidiaries including DAVA) refused to accept the available Doxycycline supply, Chartwell attempted to rescind its agreement with DAVA in order to find other generic drug marketers, which Chartwell claims it was able to accomplish.

- "reduc[e] prices for consumers, all while earning significant profits." But DAVA (and, subsequently, Endo and Par) withheld Doxycycline supply from the market and priced its Doxycycline at the supracompetitive price of its co-conspirators. Chartwell suggested a reason for Endo's economically irrational decision to withhold additional Doxycycline supply when there was ample demand in the market. It accused Endo and its generic subsidiaries of engaging in an illegal price-fixing and market allocation scheme: "Having bought DAVA, Endo implemented its withhold-and-price-gouge scheme, did virtually nothing to sell the Chartwell Entitites' Doxy, and, in collusion with its alleged 'competitors,' set Doxy's price at the *exact same* level its competitors were charging for the drug." (emphasis in original). Chartwell further alleged that "DAVA and Moezinia dedicated efforts to *withhold* [Doxycycline] from the marketplace . . . to keep the overall price of Doxy high." (emphasis in original). For example, Chartwell cites to an email dated on or about July 11, 2014 where Moezinia emailed Chartwell and stated that DAVA's plan was to sell Doxycycline "slowly not to disturb pricing."
- 102. Chartwell sought discovery of the materials that Par and Endo have produced to DOJ and the State AGs. Notably, the regulators' inquiries to Endo have focused on at least three

drugs that Endo acquired rights to via DAVA: doxycycline hyclate, doxazosin mesylate, and methotrexate sodium. Chartwell and Endo settled their claims in November 2016.

### 2. Doxycycline DR

- a. Defendants' dominance over Doxycycline DR sales permitted them to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation.
- 103. Before the Doxycycline DR Class Period, Mylan was the only manufacturer of generic Doxycycline DR and had 100% of generic sales. In 2012 alone, Mylan's total revenue from direct purchases of these products was approximately . Remarkably, despite the entry of Defendants Heritage and Mayne with Doxycycline DR, Mylan's revenue in 2013 increased to and its effective price remained more or less the same through mid-2014 despite its competition.
- 104. As noted above, because each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers. In a market free from collusive activity, over time, generics' pricing would naturally near (and stay near) the generic manufacturers' marginal costs. Further, in a market free from collusive activity, the entry of a new competitor into a single player space, such as Mylan with Doxycycline DR, would result in lower prices.
- 105. But Doxycycline DR prices remained higher than expected despite the new entrants. This was a result of a collusive agreement among at least Defendants Heritage and Mylan (and, later, Mayne) to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation concerning at least Doxycycline DR. As described below, Heritage reached out to Mylan before beginning sales of Doxycycline DR to reach agreement to avoid competing on Doxycycline DR.

## b. The Doxycycline DR scheme.

- 106. Evidence unearthed in the State AGs' investigation shows that Defendants Heritage, Mayne, and Mylan routinely sought out their competitors in an effort to reach agreement to engage in market and customer allocation, maintain high prices, and avoid competing on price. This agreement had the effect of artificially maintaining high prices for a large number of generic drugs, including Doxycycline DR, and creating an appearance of competition when in fact none existed.
- 107. In 2013 and 2014, Malek, then-President of Defendant Heritage, and Glazer, then-CEO and Chairman of Defendant Heritage, compiled a large list of generic drugs, including Doxycycline DR, and instructed employees to contact competitors to reach agreement to fix prices and allocate customers. Malek was responsible for contacting Defendant Mylan and did so with respect to a number of drugs, including Doxycycline DR. Heritage employees also contacted competitors and reached agreements to fix, maintain, and stabilize the prices, rig bids, and allocate market and customers for Doxycycline DR, as well as other generic drugs.
- 108. In May 2013, as Heritage was gearing up to launch Doxycycline DR, Heritage executives engaged in communications with various executives at Mylan, which was then the only manufacturer of Doxycycline DR. For example, Malek asked another executive at Heritage to set up a call between Malek and the Vice President of Sales at Mylan, Bob Potter ("Potter"). Malek and Potter frequently attended the same industry events. For example, both attended the NACDS Store Expo held every August throughout the Class Period. The other Heritage executive recommended that Malek contact Jan Bell ("Bell") Director, National Accounts at Mylan. Malek promptly connected with Bell through the website LinkedIn. Malek and Bell communicated by phone on multiple occasions and continued to communicate about various

drugs including Doxycycline DR. Also in May 2013, Glazer emailed another executive at Mylan. That Mylan executive responded with a phone number where he could be reached in England, and the two spoke the next day.

- 109. During the course of these and other communications, Heritage and Mylan executives agreed to allocate market and customers, coordinate on bidding for customers, and otherwise refrain from competing with one another concerning Doxycycline DR. The objective was to avoid competition on pricing that would reduce profitability for both companies. Heritage executives made clear that the purpose of the agreement was to maintain prices.
- 110. Defendant Mayne launched Doxycycline DR in February 2014 and, just as Heritage had done with Mylan before launching Doxycycline DR, Mayne approached Heritage before beginning sales about obtaining market share and refraining from competition. For example, in January 2014, the month before Mayne entered, a Mayne employee and a Heritage employee spoke by phone.
- 111. Heritage, Mylan, and Mayne ultimately reached agreement to fix, maintain, and stabilize prices, rig bids, and allocate customers for Doxycycline DR. For example, Heritage and Mayne began coordinating on bidding. In January 2015, Econdisc Contracting Solutions, a large group purchasing organization, sought bids for Doxycycline DR, and Heritage made sure to bid a higher price than Mayne in accordance with the agreement not to compete. In September 2015, Heritage also refused to provide a Doxycycline DR bid to a large pharmacy chain because the incumbent supplier was Mayne.
- 112. The State AGs have uncovered other specific instances of anticompetitive activity among Defendants Heritage, Mayne, and Mylan, including, but not limited to:
  - An instance where Mylan agreed to "walk away" from large orders and allow Heritage to obtain the business and increase its market share.

- An instance in November 2013 where Heritage and Mylan discussed the fact that the purpose of their agreement was to maintain high prices and ensured that both companies were committed to that goal.
- An instance in February 2014 where Mayne approached Heritage to discuss engaging in market and customer allocation concerning Doxycycline.
- Instances in early to mid-2014 where Heritage and Mayne engaged in bid rigging related to Doxycycline DR.
- An instance in August 2014 where Heritage communicated with Mylan concerning their agreement to fix prices.
- An instance in November 2014 where Heritage and Mayne engaged in bid rigging related to Doxycycline DR.
- An instance in December 2014 where Heritage and Mayne employees met at a trade association conference to discuss their illegal agreement.
- An instance in December 2014 where Mayne followed through on its agreement with Heritage to rig bids on Doxycycline DR.
- An instance in December 2015 where Heritage and Mayne engaged in bid rigging related to Doxycycline DR.
- 113. In addition to these specific instances, as described below, Defendants Heritage (and its former executives Glazer and Malek) and Mylan frequently attended industry meetings and other events, which Defendants Actavis, Mayne, Par/DAVA, Sun, and West-Ward also attended.

- C. Defendants Orchestrated Their Collusion Through In-Person Meetings at Trade Association Meetings, Industry Meetings, and Other Events.<sup>45</sup>
- 114. During the Class Period, Defendants conspired, combined, and contracted to fix, raise, maintain, and stabilize prices, rig bids, and engage in market and customer allocation concerning Doxycycline, which had the intended and actual effect of causing Plaintiffs and the other members of the proposed Class to pay artificially inflated prices above prices that would exist if a competitive market had determined prices for Doxycycline.
- 115. Defendants' conduct cannot be explained by normal competitive forces. It was the result of an agreement among Defendants to fix, maintain, and stabilize prices, rig bids, and allocate customers for the sale of Doxycycline in the United States. The agreement (or agreements) was furthered by discussions held at meetings and industry events hosted by the GPhA, HDMA, ECRM, MMCAP, and NACDS as well as other meetings and communications.
- 116. In formulating and effectuating their conspiracy, Defendants engaged in numerous anticompetitive activities, including, among other things:
  - (a) Participating, directing, authorizing, or consenting to the participation of subordinate employees in meetings, conversations, and communications with co-conspirators to discuss the sale and pricing of Doxycycline in the United States;
  - (b) Participating, directing, authorizing, or consenting to the participation of subordinate employees in meetings, conversations, and communications with co-conspirators to engage in market and customer allocation or bid rigging for Doxycycline sold in the United States;
  - (c) Agreeing during those meetings, conversations, and communications to engage in market and customer allocation or bid rigging for Doxycycline sold in the United States;
  - (d) Agreeing during those meetings, conversations, and communications not to compete against each other for certain customers for Doxycycline sold in the

<sup>&</sup>lt;sup>45</sup> The allegations included in this section pertaining to the HDMA, ECRM, MMCAP, and NACDS are based in part upon documents produced to plaintiffs pursuant to subpoenas *duces tecum* issued in *In re: Propranolol Antitrust Litigation*, No. 16-cv-9901 (S.D.N.Y.).

United States;

- (e) Submitting bids, withholding bids, and issuing price proposals in accordance with the agreements reached;
- (f) Selling Doxycycline in the United States at collusive and noncompetitive prices; and
- (g) Accepting payment for Doxycycline sold in the United States at collusive and noncompetitive prices.
- adhering to the collective scheme. Here, such communications occurred primarily through (1) trade association meetings and conferences, (2) private meetings, dinners, and outings among smaller groups of employees of various generic drug manufacturers, and (3) individual private communications between and among Defendants' employees through use of the phone, electronic messaging and similar means.
- 118. These secret, conspiratorial meetings, discussions, and communications helped to ensure that all Defendants agreed to participate in, implement, and maintain an unlawful bid rigging, price-fixing, and market and customer allocation scheme.
- has reportedly obtained information regarding the investigation of generic drug companies by the DOJ, and has indicated that the DOJ is investigating the extent to which trade associations and industry conferences have been used as forums for collusion among competing generic drug companies.<sup>46</sup> The State AGs have similarly noted the centrality of trade associations and industry conferences in their investigation stating that they have uncovered evidence that certain

<sup>&</sup>lt;sup>46</sup> Eric Palmer, *Actavis gets subpoena as DOJ probe of generic pricing moves up food chain*, FIERCEPHARMA (Aug. 7, 2015), *available at* <a href="http://www.fiercepharma.com/story/actavisgets-subpoena-doj-probe-generic-pricing-moves-food-chain/2015-08-07">http://www.fiercepharma.com/story/actavisgets-subpoena-doj-probe-generic-pricing-moves-food-chain/2015-08-07</a>.

generic drug companies "routinely coordinated their schemes through direct interaction with their competitors at industry trade shows, customer conferences, and other events, as well as through direct email, phone, and text message communications."

- 120. Defendants were members of numerous trade associations, which they used to facilitate their conspiratorial communications and implement their anticompetitive scheme to raise, maintain, and stabilize prices, rig bids, and engage in market and customer allocation concerning Doxycycline, including, but not limited to, GPhA, the NACDS, and HDMA. In addition, Defendants regularly attended industry events hosted by the MMCAP.
- 121. The GPhA (now called the Association for Accessible Medicines) is the "nation's leading trade association for manufacturers and distributors of generic prescription drugs . . . ."<sup>48</sup> GPhA was formed in 2000 from the merger of three industry trade associations: the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.
- 122. GPhA's website touts, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry" and lists its "valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections." GPhA's "member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year."

<sup>&</sup>lt;sup>47</sup> CTAG Website, Press Release, 40 State Attorneys General Now Plaintiffs in Federal Generic Drug Antitrust Lawsuit (Mar. 1, 2017), available at http://www.ct.gov/ag/cwp/view.asp?Q=588538&A=2341.

<sup>&</sup>lt;sup>48</sup> GPhA, *Membership*, <a href="http://web.archive.org/web/20150413013008/http://www.gphaonline.org:80/about/membership.">http://web.archive.org/web/20150413013008/http://www.gphaonline.org:80/about/membership.</a>

<sup>49</sup> *Id*.

- 123. Several of Defendants' high-ranking corporate officers have served on GPhA's Board of Directors before and during the Class Period:
- 124. **2012 Board of Directors**: Tony Mauro, President of Mylan Inc.; Doug Boothe, President and CEO, Actavis, Inc., Jeffrey Glazer, CEO of Heritage;
- 125. **2013 Board of Directors:** Tony Mauro, President of Mylan Inc.; Charlie Mayr, Chief Communications Officer Global, Actavis, Inc.; Jeffrey Glazer, CEO of Heritage;
- 126. **2014 Board of Directors:** Jeffrey Glazer, CEO of Heritage; Tony Mauro, President of Mylan Inc.;
- 127. **2015 Board of Directors:** Jeffrey Glazer, CEO of Heritage; Marcie McClintic Coates, VP & Head of Global Regulatory Affairs for Mylan; and Tony Pera, Chief Commercial Officer of Par; and
- 128. **2016 Board of Directors:** Heather Bresch, CEO of Mylan; Tony Pera, Chief Commercial Officer of Par; and Jim Kedrowski, Executive VP of Sun.
- 129. Defendants Actavis, Sun, West-Ward, Heritage and Mylan were regular members of the GPhA during the Class Period, while DAVA Pharmaceuticals was an associate member. Regular members "are corporations, partnerships or other legal entities whose primary business derives the majority of its revenues from sales of (1) finished dose drugs approved via ANDAs; (2) products sold as authorized generic drugs; (3) biosimilar/biogeneric products; or (4) DESI products."<sup>50</sup>
- 130. The NACDS is a national trade association representing chain community pharmacies. Its members include generic drug manufacturers, wholesalers, and retail chain pharmacies. NACDS holds regular industry events, including annual and regional conferences,

 $<sup>^{50}</sup>$  *Id*.

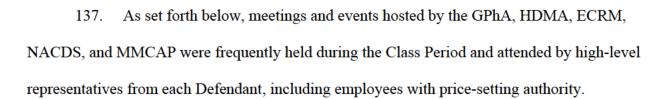
which Defendants and other generic drug manufacturers attended, including the annual Total Store Expo.

- 131. The HDMA (now called HDA) is a national trade association that represents "primary pharmaceutical distributors" which links the nation's drug manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, and clinics.<sup>51</sup> HDMA holds regular conferences where its members, including generic drug manufacturers, meet to discuss various issues affecting the pharmaceutical industry. HDMA members during the Class Period have included Defendants Actavis, Heritage, Sun, and Mylan.
- organization for government facilities that provide healthcare services. MMCAP has been delivering pharmacy and healthcare value to members since 1985. MMCAP's membership extends across nearly every state in the nation, delivering volume buying power. Members receive access to a full range of pharmaceuticals and other healthcare products and services; such as, medical supplies, influenza vaccine, dental supplies, drug testing, wholesaler invoice auditing and returned goods processing."
- Administration, an agency of the State of Minnesota, began a cooperative purchasing venture program to procure pharmaceutical products at the best price possible for the benefit of any other state interested in participating in the program . . . In 1996, the cooperative purchasing venture was named Minnesota Multistate Contracting Alliance for Pharmacy . . . and currently provide healthcare-related contracting to state and local government members located across the United

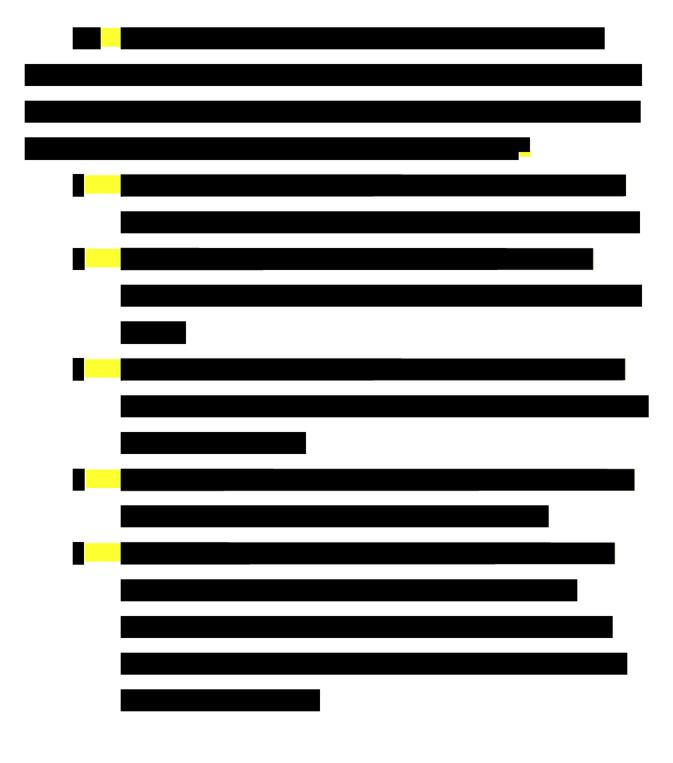
<sup>&</sup>lt;sup>51</sup> HDA, About, available at https://www.healthcaredistribution.org/about.

State of America. Total purchasers by MMCAP member facilities for all MMCAP programs exceed \$1 billion annually . . . ."

- 134. According to its website, ECRM conducts Efficient Program Planning Sessions that are made up of one-on-one strategic meetings that connect decision makers in an effort to maximize time, grow sales, and uncover industry trends.
- 135. At annual meetings organized by ECRM, generic drug manufacturers have scheduled meetings with generic drug buyers at chain drug stores, supermarkets, mass merchants, wholesalers, distributors, and buy groups for independents.



- 138. For example, on October 1-3, 2012, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from at least Defendants Actavis, Heritage, Par, Sun, and Mylan, as well as Endo Pharmaceuticals.
- 139. On February 20-22, 2013, GPhA held its Annual Meeting in Orlando, Florida that was attended by representatives from Defendants Actavis, Heritage, Par, and Mylan, as well as DAVA Pharmaceuticals, URL Pharma, Endo, and Qualitest, including at least the following key executives:
  - a. Actavis: Siggi Olafsson, President; and
  - b. Mylan: Tony Mauro, President, Mylan Inc.





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- 141. On April 20-23, 2013 NACDS held its 2013 Annual Meeting at the Sands Expo Convention Center in Palm Beach, Florida. NACDS's 2013 Annual Meeting was attended by representatives from Defendants, including at least the following key executives for generic drug sales and pricing:<sup>53</sup>
  - a. Actavis: Andrew Boyer, President & CEO, North America Generics; Sigurdur Olafsson, President & CEO, Global Generics; Robert Stewart, COO; Michael Baker, Executive VP, Trade Sales & Development;
  - Endo: Scott Littlefield, Trade Director; and Brent Bumpas, National Account
     Director Trade;
  - c. **Mylan**: Joe Duda, President, Mylan Pharmaceutical; Robert Potter, SVP N.A.

    National Accounts and Channel Development; Tony Mauro, President, Mylan Inc.;

    Jim Nesta, VP, Sales;
  - d. Par: Jon Holden, VP Sales; Paul Campanelli, President; Michael Altamuro, Vice
     President, Marketing & Business Analytics; Renee Kenney, Senior Advisor
     Generic Sales;
  - e. Sun: GP Singh Sachdeva, President of Sun Pharmaceuticals, USA; and

<sup>&</sup>lt;sup>53</sup> The NACDS holds an annual meeting every year including between April 21-24, 2012. Plaintiffs do not yet have discovery from the NACDS for dates earlier than January 2013, but based upon their regular attendance later in the conspiracy period, the 2012 event is believed to have been attended by, at least, Defendants Actavis, Mylan, and Sun.

- f. URL Pharma: Bill Everett, National Trade Account Manager.
- 142. On June 2-5, 2013, HDMA held its 2013 Business and Leadership Conference ("BLC") in Orlando, Florida. HDMA's June 2013 BLC was attended by representatives from each of the Defendants and other relevant entities, including at least the following key executives for generic drug sales and pricing:<sup>54</sup>
  - a. Actavis: Andrew Boyer, SVP, Generic Sales & Marketing; Marc Falkin, VP,
     Purchasing; Maureen Barrett, Director, National Accounts; Anthony Giannone,
     National Accounts Director;
  - b. **Endo**: John Bullock, National Accounts Director;
  - c. **Heritage**: Neal O'Mara, National Accounts Manager; and Anne Sather, National Account Manager;
  - d. **Mutual:** David Moody, Chief Executive Officer;
  - e. Mylan: Janet Bell, National Accounts Director; Joseph Duda, President of Mylan Pharmaceuticals; Edgar Escoto, National Accounts Director; Kevin McElfresh, Executive Director, National Accounts; James Nesta, Executive Director, National Accounts; Robert O'Neill, VP; Sean Reilly, Key Account Manager; John Shane, Director National Trade Accounts; Gary Tighe, National Accounts Director; Lance Wyatt, National Accounts Director; Michael Aigner, National Account Director;

<sup>&</sup>lt;sup>54</sup> The HDMA holds a BCL every year, including in June 2012. Plaintiffs do not yet have discovery from the HDMA for dates earlier than January 2013, but based upon their attendance in 2013, the 2012 event is believed to have been attended by all Defendants.

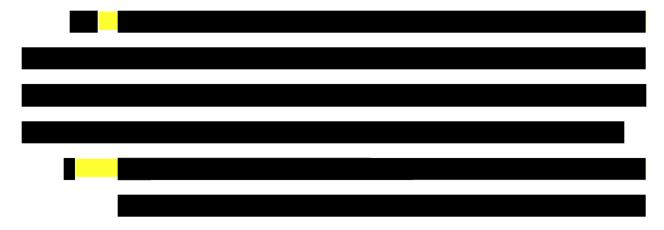
- f. Par: Jon Holden, VP Sales; Sandra Bayer, Senior National Accounts Executive;

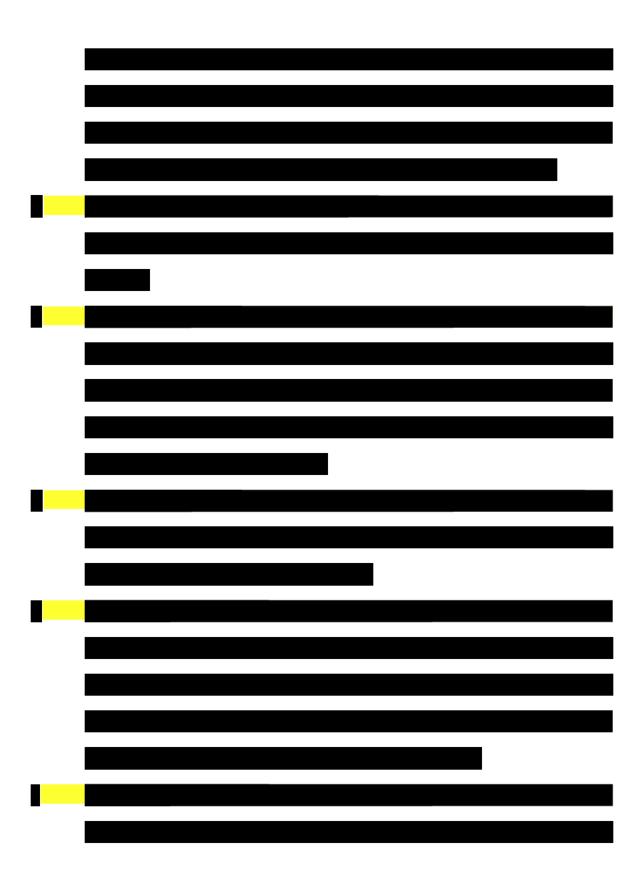
  Peter Gargiulo, Director, National Accounts; Christopher Neurohr, Director,

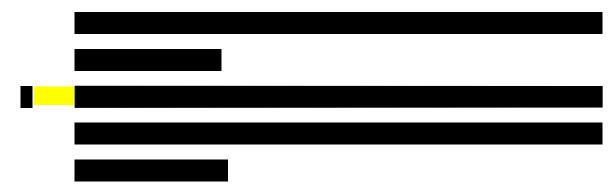
  National Accounts;
- g. **Sun**: Scott Littlefield, National Account Director; Daniel Schober, Associate Vice President, Trade Sales; David Moody, Chief Executive Officer of Mutual Pharmaceutical Company, Inc. ("Mutual"), a wholly-owned subsidiary of Sun; David Simoneaux, Marketing Coordinator of Mutual; and
- West-Ward: Mark Boudreau, Executive Director of National Sales; Paul Kersten,
   VP, Sales & Marketing; Neal Gervais, National Account Director; Joseph Ruhmel,
   National Account Director; Steven Snyder, National Account Director; and John
   Kline, National Account Director.
- 143. On June 3-4, 2013, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from at least Defendants Actavis, Heritage, Mylan, Par, and Sun, as well as Endo and Qualitest.
- 144. On August 10-13, 2013, NACDS held its 2013 Total Store Expo at the Sands Expo Convention Center in Las Vegas, Nevada. NACDS's August 2013 Total Store Expo was attended by at least the following representatives from Defendants, and other relevant entities, who were key executives for generic drug sales and pricing:
  - a. Actavis: Michael Baker, Executive VP, Trade Sales & Development; Andrew Boyer, President & CEO N.A. Generics; Napolean Clark, Vice President, Marketing; Michael Dorsey, Director, National Accounts; Marc Falkin, Senior Vice President, Sales; Anthony Giannone, Executive Director Sales; Megan

- Gorman, Senior Marketing Manager; Maureen Meehan, Director, National Account; Cindy Stevens, Director, National Accounts;
- DAVA: Rich Franchi, Vice President, Sales; Kim Rothofsky, Senior Director,
   Trade Relations;
- c. Endo: Scott Littlefield, Trade Director; Brent Bumpas, National Accounts Director
   Trade;
- d. Heritage: Allen Dunehew, President/CEO; Matthew Edelson, Senior Director of Sales; Jeffrey A. Glazer (then CEO and Chairman); Jason T. Malek, SVP (then Senior Vice President, Commercial Operations, and subsequently President); Gina Gramuglia, Commercial Operations; Neal O'Mara, Senior Director, National Accounts; Anne Sather, Senior Director, National Accounts;
- e. **Mylan**: Mike Aigner, Director National Accounts; Kevin McElfresh, Executive Director National Accounts; Joe Duda, President of Mylan Pharmaceuticals; Jim Nesta, VP, Sales; Robert Potter, Senior Vice President North America National Accounts and Channel Development; Rob O'Neill, Head of Sales; Lance Wyatt, Director National Accounts; Edgar Escoto, Director, National Accounts;
- f. Par: Jon Holden, Vice President, Sales; Renee Kenney, Senior Advisor Generic Sales; Karen O'Connor, Vice President, National Accounts; Michael Altamuro, Vice President, Marketing & Business Analytics; Gerald Burton, Vice President, National Accounts; Christine Caronna, Director, National Accounts; Rick Guillory, Vice President, National Accounts;
- Qualitest: Warren Pefley, Vice President, Sales & Marketing; Charles Probst, Vice
   President; Kelly Bachmeier, Director, National Accounts; Sandra Bayer, Senior

- Director, National Accounts; James Burnett, National Accounts Manager; Walter Busbee, Director National Accounts; Lori Minnihan, Associate Director, Trade Pricing Operations; Spike Pannell, National Account Manager;
- h. Sun: GP Singh, President; William Everett, National Trade Account Manager;
   Wayne Fallis, Director National Accounts; Steven Goodman; Director Marketing
   Generics; Susan Knoblauch, Senior Manager, Sales; Grace Shen, Vice President,
   Marketing; and Steven Smith; Senior Director of Sales; and
- West-Ward: Tareq Darwazeh, National Account Senior Manager; Spiro Gavaris,
   Vice President, Sales & Marketing; Sam Goodman, Marketing Manager; Paul
   Markowitz, Director National Accounts.
- 145. On October 28-30, 2013, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from at least Defendants Actavis, Heritage, Par, Sun, and Mylan, as well as Endo and Qualitest.
- 146. On February 19-21, 2014, GPhA held its Annual Meeting in Orlando, Florida that was attended by representatives from at least Defendants Actavis, Heritage, Par, Sun, and Mylan, as well as DAVA, Endo and Qualitest, including at least Tony Mauro, President, Mylan Inc., among other key executives.







- 148. On April 26-29, 2014, NACDS held its 2014 annual meeting in Scottsdale, Arizona. NACDS's 2014 annual meeting was attended by at least the following representatives from Defendants, and other relevant entities, who were key executives for generic drug sales and pricing:
  - a. Actavis: Andrew Boyer, President and CEO NA Generics; Marc Falkin, Senior
     Vice President, Sales; Sigurdur Olafasson, President & CEO Global Generics
     Medicines; Robert Stewart, Chief Operating Officer;
  - Endo: Scott Littlefield, Trade Director; Brent Bumpas, National Accounts Director
     Trade;
  - c. **Heritage**: Jeffrey Glazer (then CEO and Chair);
  - d. Mylan: Joe Duda, President, Mylan Pharmaceuticals; Tony Mauro, President, Mylan Inc.; Robert Potter, Senior Vice President North America National Accounts and Channel Development; Rob O'Neill, Head of Sales; Hal Korman, EVP & COO; Jim Nesta, VP, Sales;
  - e. **Par:** Paul Campanelli, President; Antonio Pera, Chief Commercial Officer; Jon Holden, Vice President, Sales; Renee Kenney, Senior Advisor Generic Sales; Michael Altamuro, Vice President, Marketing & Business Analytics; and

- f. Sun: GP Singh Sachdeva, President; Steven Goodman; Director Marketing Generics; and Steven Smith; Senior Director of Sales.
- 149. On May 12-15, 2014, MMCAP held its National Member Conference in Bloomington, Minnesota. At MMCAP's 2014 National Member Conference, topics included "RFPs under consideration for Pharmacy," "contract evaluation," and "pharmaceutical price increases." At the MMCAP conference, a Heritage employee met in person and discussed price increase strategies with a number of different competitors and was able to personally confirm agreement to raise prices of at least one drug (Glyburide).
- 150. MMCAP's May 12-15, 2014 National Member Conference was attended by the following representatives from Defendants, who were key executives for generic drug sales and pricing:
  - a. Actavis: Mark Blitman, Executive Director of Sales for Government Markets;
  - b. Mylan: Jan Bell, Director, National Accounts; and
  - c. Heritage: Anne Sather, Director, National Accounts.
- 151. On June 1-4, 2014, the HDMA held a BLC at the JW Marriott Desert Ridge in Phoenix, Arizona. The June 1-4, 2014 BLC was attended by the following representatives from Defendants, and other relevant entities, who were key executives for generic drug sales and pricing:
  - a. **Actavis:** Maureen Barrett, Director, National Accounts U.S. Generics; Marc Falkin, Vice President, Marketing, Pricing & Contract Operations; John Fallon, Director, National Accounts; Anthony Giannone, Executive Director, Sales;
  - Mylan: Richard Issac, Senior Manager, Strategic Accounts; Lance Wyatt, Director,
     National Accounts; Michael Aigner, National Account Manager; John Baranick,

- Director, Trade Relations; Joseph Duda, President, Mylan Pharmaceuticals; Edgar Escoto; Director National Accounts; Joseph Zenkus, Vice President, North America Sales & Channel Strategy; James Nesta, VP, Sales; Karen O'Connor, Director, National Accounts;
- Par: Sandra Bayer, Senior National Account Executive; Peter Gargiulo, Director,
   National Accounts;
- d. **Sun:** Scott Littlefield, National Account Executive; Daniel Schober, Associate Vice President, Trade Sales; Steven Smith, Director of Sales; Susan Knoblauch, Senior Manager, Sales;
- e. **West Ward:** Mark Boudreau, Executive Director of National Sales; John Kline, National Account Director, Joseph Ruhmel, National Account Director; Steven Snyder, National Account Director; and
- f. **Heritage**: Neal O'Mara, Senior Director, National Accounts; Anne Sather, Associate Director, National Accounts.
- 152. On June 3-4, 2014, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from at least Defendants Actavis, Heritage, Par, Sun, and Mylan, as well as Qualitest.
- 153. On August 23-26, 2014, NACDS held its 2014 Total Store Expo at the Boston Convention Center in Boston, Massachusetts. NACDS's August 2014 Total Store Expo was attended by at least the following representatives from Defendants, who were key executives for generic drug sales and pricing:
  - a. Actavis: Andrew Boyer, President & CEO North American Generics; David Buchen, Executive Vice President Commercial, North America Generics &

International; Napoleon Clark, Vice President, Marketing; Ashley Delponte, Manager, Trade Marketing, Sales & Marketing; Michael Dorsey, Director National Accounts; Marc Falkin, Senior Vice President, Sales; Anthony Giannone, Executive Director, Sales; Megan Gorman, Manager, Marketing Senior; Rob Hooper, Senior Marketing Manager; Randy Hurst, Senior Vice President & General Manager; Christina Koleto, Manager, Pricing Senior; Maureen Meehan; Director National Accounts; Paul Reed, Senior Director, Trade Sales & Development; Richard Rogerson, Senior Director New Products, Business Analytics & Systems; Violet Saakyan, Marketing Manager; Eric Schultz, Senior Marketing Manager; Cindy Stevens, Director, National Accounts;

- b. **Heritage**: Heather Beem, National Accounts Manager, Institutional; Katie Brodowski, Associate Director Institutional Sales; Matthew Edelson, Senior Director of Sales; Jeffrey A. Glazer (then CEO and Chairman), Jason T. Malek, SVP (then Senior Vice President, Commercial Operations, and subsequently President); Gina Gramuglia, Commercial Operations; Neal O'Mara, Senior Director, National Accounts; Anne Sather, Senior Director National Accounts;
- Mayne: Stefan Cross: President; Gloria Schmid, Director of National Accounts;
   Chris Schneider, Executive Vice President, Generic Product Division; Melissa
   Gardner, National Account Executive;
- d. Mylan: Joe Duda, President; Robert Potter, Senior Vice President North America National Accounts; Mike Aigner, Director, National Accounts; Tony Mauro, CCO; Kevin McElfresh, Executive Director, National Accounts; Gary Tighe, Director, National Accounts; Lance Wyatt, Director, National Accounts; Jim Nesta, VP,

- Sales; Sean Reilly, National Account Manager; Michael Scouvart, Head of Marketing North America;
- e. Par: Michael Altamuro, Vice President, Marketing & Business Analytics; Gerald Burton, Vice President, National Accounts; Christine Caronna, Director, National Accounts; Rick Guillory, Vice President, National Accounts; Jon Holden, Vice President, Sales; Renee Kenney, Senior Advisor Generic Sales; Karen O'Connor, Vice President, National Accounts; Antonio Pera, Chief Commercial Officer; and
- f. Sun: GP Singh Sachdeva, President; Wayne Fallis, Director, National Accounts; Steven Goodman, Director, Marketing Generics; Donna Hughes, National Account Manager; Susan Knoblauch; Senior Manager, Sales; Jolene McGalliard, National Account Manager; Anand Shah, Director, Strategic Pricing and Marketing; Grace Shen, Vice President, Marketing; Steven Smith, Senior Director of Sales; and
- g. West Ward: Spiro Gavaris, Vice President, Sales and Marketing; Sami Goodman, Marketing Manager; Elizabeth Guerrero, Director, National Accounts; Paul Markowitz, Director, National Accounts; Joel Rosenstack, Senior Director, Marketing; Doug Statler, Senior Director, Head of Sales.
- 154. On October 27-29, 2014, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from at least Defendants Actavis, Heritage, Mylan, Par, Sun, and West Ward, and Qualitest.
- 155. In 2015, and 2016, Defendants continued to regularly attend trade association meetings, conferences and events, including: (i) the February 9-11, 2015 GPhA Annual Meeting in Miami, Florida;

(iv) the June 7-10, 2015 HDMA BLC

in San Antonio, Texas; (v) the June 9-10, 2015 GPhA meeting in Bethesda, Maryland; (iv) the August 22-25, 2015 NACDS Total Store Expo in Denver, Colorado; (v) the November 2-4, 2015 GPhA meeting in Bethesda, Maryland; (vi) the June 12-16, 2016 HDMA BLC in Colorado Springs, Colorado; and (vii) the August 6-9, 2016, NACDS 2016 Total Store Expo in Boston, Massachusetts.

- and trade shows, representatives from at least some Defendants, as well as other generic drug manufacturers, discussed their respective businesses and customers. These discussions would occur at social events, including lunches, cocktail parties, dinners, and golf outings, that usually accompanied these conferences and trade shows. Defendants' employees used these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers.<sup>55</sup>
- 157. In conjunction with meetings at conferences and trade shows, representatives of generic drug manufacturers get together separately, in more limited groups, allowing them to further meet face-to-face with their competitors and discuss their business. In fact, high-level executives of many generic drug manufacturers get together periodically for what at least some of them refer to as "industry dinners."<sup>56</sup>
- 158. A large number of generic drug manufacturers, including many Defendants here, are headquartered in close proximity to one another in New York, New Jersey, and eastern Pennsylvania, giving them easier and more frequent opportunities to meet and collude. For

<sup>&</sup>lt;sup>55</sup> See, e.g., Amended Complaint (Public Version), Connecticut v. Aurobindo Pharma USA, Inc., No. 16-cv-2056, ECF 168 (D. Conn.), at ¶¶ 50-52, available at <a href="http://www.ct.gov/ag/lib/ag/press">http://www.ct.gov/ag/lib/ag/press</a> releases/2016/20161215 gdms complain.pdf.

<sup>&</sup>lt;sup>56</sup> *Id.* at ¶¶ 53-60.

example, in January 2014, at a time when the prices of a number of generic drugs were reportedly soaring, at least thirteen high-ranking male executives, including CEOs, Presidents, and Senior Vice Presidents of various generic drug manufacturers, met at a steakhouse in Bridgewater, New Jersey.

- 159. Generic drug manufacturer employees also get together regularly for what is referred to as a "Girls' Night Out" ("GNO"), or alternatively "Women in the Industry" meetings and dinners. During these GNOs, meetings and dinners, these employees meet with their competitors and discuss competitively sensitive information. For example, several different GNOs were held in 2015, including: (1) in Baltimore, Maryland in May, and (2) at the NACDS conference in August.
- 160. Through these various interactions, Defendants' employees are often acutely aware of their competition and, more importantly, each other's current and future business plans. This familiarity and opportunity often leads to agreements among competitors to fix prices or to allocate a given market so as to avoid competing with one another on price.
- 161. Defendants also routinely communicate and share information with each other about bids and pricing strategy. This can include forwarding bid packages received from a customer (*e.g.*, a Request for Proposal or "RFP") to a competitor, either on their own initiative, at the request of a competitor, or by contacting a competitor to request that the competitor share that type of information.
- 162. Additionally, Defendants share information regarding the terms of their contracts with customers, including various terms relating to pricing, price protection, and rebates. Defendants use this information from their competitors to negotiate potentially better prices or terms with their customers, which could be to the ultimate detriment of consumers.

- 1. Investor communications demonstrate Defendants' intent to fix and maintain supracompetitive prices.
- 163. Defendants' public statements and admissions in their investor communications show that Defendants realized record revenues during the Class Period and emphasize a commitment to increasing generic pharmaceutical prices as well as maintaining them at supracompetitive levels.
- 164. **Actavis**: During Actavis' October 29, 2013 earnings call, Actavis Director Sigurdur Olafsson stated: "But there's opportunities to take pricing increases, and that is what has changed since maybe five years ago when there wasn't an opportunity."
- 165. During Actavis' August 5, 2014 earnings call, Actavis EVP David Buchen stated: "We have a very broad portfolio and we take pricing opportunities where we can."
- 166. During Actavis' May 11, 2015 earnings call, Actavis CEO Brenton Saunders stated:
  - So let me tackle generic pricing. . . . We haven't seen much of a change despite all the fanfare and publicity around drug pricing in generics. There are obviously a few products that go up. But the model for generics is price decreases as more competitors come into the market. That's just the way the business works. . . . That being said, the environment has remained pretty stable and favorable. So we don't expect that to change short term either.
- 167. On August 6, 2015, Saunders stated on an earnings call that the generics business "is doing very well, and the units that comprise it are firing on all cylinders as we prepare for the combination with Teva."
- 168. Actavis reported rising revenues in its United States generics business during the Class Period.
- 169. **Mayne:** In an August 28, 2015 FY15 Results Presentation, Mayne reported that U.S. "revenue uplift [was] driven by," among other products, Doxycycline.

- 170. In a September 9, 2015 Company Presentation, Mayne reported that it would be able to optimize Doxycycline sales through "[f]urther product pricing improvements."
- 171. **Mylan:** On October 25, 2012, Mylan's CEO Heather Bresch stated in an earnings call: "You've heard me quarter after quarter coming and saying we weren't going to chase the bottom, that there's been irrational behavior and that we would continue to hold steady and control what we can control."
  - 172. On February 27, 2013, Mylan's CFO, John Sheehan, stated in an earnings call:

2013 will yet be another strong year for Mylan. In the U.S., we are anticipating a high volume of new product launches, and we expect to once again be agile enough to quickly seize new supply opportunities when they become available. In addition, favorable changes to the regulatory environment, including increased resources to expedite product reviews and greater oversight with respect to manufacturing, as well as an anticipated more stable pricing environment resulting in part from continued consolidation within the industry, are just two of the favorable macroeconomic factors that we see in 2013.

- 173. On May 2, 2013, Bresch stated in an earnings call: "From my perspective, we see the generic industry alive and well. We still see a lot of runway room here in the United States."
- 174. On May 1, 2014, Bresch stated in an earnings call: "We continue to see stability really across our entire generic line on pricing."
  - 175. On August 7, 2014, Bresch stated in an earnings call:

As far as pricing, look, I think that, that stability in our North American – that core business is certainly why we're able to deliver the results we have today, which, like I said, despite those product delays, we see growth year-over-year. We've seen North America continue to maximize opportunities.

176. On October 30, 2015, Sheehan stated in an earnings call:

With respect to gross margin, I guess I would start by pointing out that since 2010 our gross margins have increased from 45% up to the high end of the guidance range that we indicated we would be at

- this year of 55%. So the gross margins have been sustained. They have steadily increased over the last five, six years. . . . It also has been driven by the positive pricing environment that we've seen, especially over the last couple of years in North America.
- 177. During the same call, Bresch stated: "Look, I would say as far as price increases, we've had a very consistent approach. We have absolutely had opportunities around generic pricing."
- 178. On February 10, 2016, Bresch stated in an earnings call her belief that Mylan had been "a very responsible generic player with hundreds of products into the market and have shown very responsibly [sic] price erosion."
- 179. Mylan reported rising revenues in its United States generics business during the Class Period.
- 180. **Par:** During Endo's May 1, 2014 earnings call, Endo CEO Rajiv De Silva stated that Endo's generics business (Par) was performing strongly in part because "we have been able to take advantage of some pricing opportunities."
- 181. On July 31, 2014, Endo's CEO Rajiv De Silva stated in an earnings call that in the generics business "there are certain specific situations and market opportunities which we take advantage of, as do our competitors.
- 182. On March 2, 2015, Silva stated in an earnings call that "pricing actions give us some gross margin benefit."
- 183. In a May 18, 2015 presentation by Endo International plc concerning its acquisition of Par, Endo noted that "consolidation and maturation of competitors have stabilized the pricing environment" for generic pharmaceuticals in the U.S.

- 184. On August 8, 2016, Par's President Paul Campanelli stated in response to a question about the generics environment: "And typically you want to just be very careful about trying to go after too much share. You just have got to take a balanced approach."
- 185. Par reported rising revenues in its United States generics business during the Class Period.
- 186. **Sun**: On November 14, 2013, during an earnings call, Sun's Managing Director Dilip Shanghvi sated in response to an analyst question concerning generic drug manufacturers' "opportunities [to take] price hikes across portfolio that seems to becoming a little more widespread sort of a thing" that "price increases [are] becoming kind of more widespread than what it used to be historically, so clearly there would be some impact going forward."
- 187. During the same earnings call, another Sun executive stated that Sun has been "warning" about "sustaining the price [increases], but we have been proved wrong so far."
- 188. On February 13, 2014, Sanghvi stated in an earnings call that Sun continued "to enjoy the benefits of favourable [sic] pricing for certain generic products in the US." On the same call, an analyst also noted that Sun "had some good price increases in select products after [Sun's] purchase of [the URL/Mutual] portfolio."
- 189. In 2013, Sun's subsidiary URL "had undertaken price hikes in March" and, as a result of these price increases, Sun estimated "\$60-80 million (of \$128 million in total revenue for URL estimated . . . for FY[20]14) to come from [Doxycycline], with operating margins in the range of 50-55 percent."<sup>57</sup>

<sup>&</sup>lt;sup>57</sup> Ujjval Jauhari, *Sun Pharma's Prospects Remain Bright*, Business Standard (Sept. 12, 2013), *available at* <a href="http://www.business-standard.com/article/markets/sun-pharma-s-prospects-remain-bright-113091200894">http://www.business-standard.com/article/markets/sun-pharma-s-prospects-remain-bright-113091200894</a> 1.html.

- 190. In 2013 and 2014, Sun reported that its costs were stable. In its quarterly reports during that period, Sun's directors reported that the company's material cost and other expenditures as a percentage of net sales, as well as staff costs, were substantially the same or lower than the same periods in the prior year. For example, Sun reported that net sales increased 40% in fiscal year 2013 compared to 2012 even while "[m]aterial cost, as a percentage of the net sales is 18.5% which is lower as compared to the previous year." Staff costs and other expenditures were also reported to be lower in 2013. Similarly, Sun reported that second quarter 2013-14 costs were also "in-line with Q2 last year."
- 191. Sun reported in September 2015 and February 2016 investor presentations that one of the "key drivers" of its sales through the period 2012 through 2014 was Doxycycline, which it described as a "low competition product" in the U.S. a notable description in light of the large number of competitor products.
- 192. Sun reported rising revenues in its United States generics business during the Class Period.
- 193. **West-Ward:** In 2013, Hikma, parent company to West-Ward, reported that "[s]trong cash flow reflects exceptional profitability of doxycycline." <sup>58</sup>
- 194. On March 12, 2014, Hikma announced strong revenue growth, driven in part by Doxycycline sales, and forecasted continued growth in 2014, which would reflect continued commitment to maintaining its Doxycycline pricing. Said Darwazah, Hikma's CEO was "confident about the prospects for 2014," and noted that in 2013, "[o]ur Generics business

<sup>&</sup>lt;sup>58</sup> 2013 Hikma Pharmaceuticals Preliminary Results.

delivered very strong revenue, driven primarily by doxycycline, and generated significant cash flow."<sup>59</sup>

- 195. In Hikma's Q2 2014 earnings call, Hikma's CFO stated: "I don't know how many of you have covered U.S. generic companies. But when I look at competitors, I look at the -- most companies that are either U.S. based or have a strong position in the U.S. are doing very well the last few years. So the market forces are changing, I believe, in the market."
- 196. In December 2013, Darwazah told Bloomberg Business that West-Ward's huge increases in Doxycycline prices were justified because it was "forced' to raise prices because its competitors raised theirs."
- 197. West-Ward reported rising revenues in its United States generics business during the Class Period.
  - 2. Industry commentary indicates Defendants' collusion is a plausible explanation for the increase in Doxycycline price
- 198. Comments from industry analysts suggest manufacturers' alternative explanations for the price hikes (*e.g.*, supply disruptions) are mere pretext, intended to shroud the Defendants' conspiratorial conduct and ends. For instance, Richard Evans at Sector & Sovereign Research wrote:

A plausible explanation [for price increases] is that generic manufacturers, having fallen to near historic low levels of financial performance are cooperating to raise the prices of products whose characteristics – low sales due to either very low prices or very low volumes – accommodate price inflation.<sup>61</sup>

<sup>&</sup>lt;sup>59</sup> Press Release, Hikma Pharmaceuticals plc (Mar. 12, 2014).

<sup>&</sup>lt;sup>60</sup> Alan Katz, *Surprise! Generic Drug Prices Spike*, BLOOMBERG (Dec. 12, 2013), available at <a href="https://www.bloomberg.com/news/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise">https://www.bloomberg.com/news/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise</a>.

<sup>&</sup>lt;sup>61</sup> See Ed Silverman, Generic Drug Prices Keep Rising, but is a Slowdown Coming?, WALL STREET JOURNAL (Apr. 22, 2015), available at <a href="http://blogs.wsj.com/pharmalot/2015/04/22/generic-drug-prices-keep-rising-but-is-a-slowdown-coming/">http://blogs.wsj.com/pharmalot/2015/04/22/generic-drug-prices-keep-rising-but-is-a-slowdown-coming/</a>.

199. According to one study, since 2013 approximately one in 19 generic drugs sold in the United States have undergone major price hikes that may be consistent with collusion:

Fideres Partners LLP, a London-based consultancy that works with law firms to bring litigation against companies, reported "anomalous pricing patterns" in scores of generic drugs sold in the U.S. from 2013 to 2016. It identified 90 medicines whose prices rose at least 250 percent over the three-year period and were increased by at least two drug companies around the same time, even though there was no obvious market reason for the increases. The average price jump among the 90 drugs was 1,350 percent, Fideres found.

"I don't think the public or even the politicians in the U.S. have any idea just how widespread and extreme the phenomenon is," said Alberto Thomas, one of Fideres's founders. 62

- 200. Another study concluded that in 2014: "292 generic medication listings went up by 10% or more, 109 at least doubled in price and 14 went up by ten or more times in price that year." The GAO Report also noted similar "extraordinary price increases" across many generic drugs, including Doxycycline, in recent years that could not be linked to any particular cause.
- 201. Pennsylvania physicians through the Pennsylvania Medical Society called on state and federal governments to investigate surging generic prices, believing anticompetitive conduct was to blame:

According to Robert Campbell MD, chair of Physicians Against Drug Shortages and immediate past president of the Pennsylvania Society of Anesthesiologists, surging prices have hit hundreds of mainstay generics, including anesthetics, chemotherapeutic agents,

<sup>&</sup>lt;sup>62</sup> Liam Vaughan and Jered S. Hopkins, *Mylan, Teva Led Peers in "Anomalous" Price Moves, Study Says*, Bloomberg (Dec. 22, 2016) *available at* <a href="https://www.bloomberg.com/news/articles/2016-12-22/widespread-drug-price-increases-point-to-collusion-study-finds">https://www.bloomberg.com/news/articles/2016-12-22/widespread-drug-price-increases-point-to-collusion-study-finds</a>.

<sup>&</sup>lt;sup>63</sup> David Belk, MD, *Generic Medication Prices, available at* http://truecostofhealthcare.net/generic medication prices/.

- antibiotics, and nutritional intravenous solutions. He believes the surging prices are a result of anti-competitive behavior.<sup>64</sup>
- D. Defendants' Conduct in Generic Drug Pricing Is Under Investigation by the United States Congress, the DOJ, and the State Attorneys General.
  - 1. Congress launched an investigation in response to news reports of a dramatic rise in the price of certain generic drugs.
- 202. As noted above, in January 2014 the NCPA sent correspondence to the United States Senate HELP Committee and the United States House Energy and Commerce Committee requesting hearings on significant spikes in generic pharmaceutical pricing.
- 203. On October 2, 2014, Senator Bernie Sanders (I-VT), Chair of the Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, and Representative Elijah E. Cummings (D-MD), the Ranking Member of the House Committee on Oversight and Government Reform, sent letters to 14 drug manufacturers, including Defendants Actavis, Heritage, Mylan, Sun, and West-Ward, requesting information about the escalating prices of generic drugs used to treat everything from common medical conditions to life-threatening illnesses.<sup>65</sup>
- 204. Senator Sanders and Representative Cummings issued a joint press release, advising "[w]e are conducting an investigation into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to life-threatening

<sup>&</sup>lt;sup>64</sup> Pennsylvania Medical Society, Press Release, *Rising Generic Drug Costs Have Physicians Raising Red Flags* (Feb. 5, 2016), *available at* <a href="http://www.prnewswire.com/news-releases/rising-generic-drug-costs-have-physicians-raising-red-flags-300216006.html">http://www.prnewswire.com/news-releases/rising-generic-drug-costs-have-physicians-raising-red-flags-300216006.html</a>.

<sup>&</sup>lt;sup>65</sup> U.S. Senator Bernie Sanders Website, Press Release, *Congress Investigating Why Generic Drug Prices Are Skyrocketing* (Oct. 2, 2014), *available at* <a href="https://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.">https://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.</a>

illnesses." They noted the "huge upswings in generic drug prices that are hurting patients" are having a "'very significant" impact threatening pharmacists' ability to remain in business. 66

205. The October Letter to Mylan, for example, states,

We are writing to your company to request information about the escalating prices it has been charging for five drugs: Albuterol Sulfate, Belnazepril/Hydrochlorothiazide, Divalproex Sodium ER, Doxycycline Hyclate, and Pravastatin Sodium . . . According to data provided by the Healthcare Supply Chain Association (HSCA), the average price charged for these drugs have increased as much as. . . 8,271 percent for Doxycycline Hyclate . . . from October 2013 to April 20014. Over that time period, the average market price went up by as much as . . . \$1,829 for Doxycycline Hyclate.<sup>67</sup>

- 206. In Mylan's October Letter, Senator Sanders and Representative Cummings requested the following information and documents from January 1, 2012, to the present:
  - (1) Total gross revenues from the company's sales of these drugs;
  - (2) The dates, quantities, purchasers, and prices paid for all sales of these drugs;
  - (3) Total expenses relating to the sales of these drugs, as well as the specific amounts for manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;
  - (4) Sales contracts or purchase agreements for active pharmaceutical ingredients for these drugs, including any agreements relating to exclusivity, if applicable;
  - (5) A description and valuation of the specific financial and non-financial factors that contributed to your company's decisions to increase the prices of these drugs;
  - (6) Any cost estimates, profit projections, or other analyses relating to the company's current and future sales of these drugs;
  - (7) Prices of these drugs in all foreign countries or markets, including price information for the countries paying the highest and lowest prices; and

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<sup>&</sup>lt;sup>66</sup> *Id* 

<sup>&</sup>lt;sup>67</sup> See Letter from Bernie Sanders, United States Senator, and Elijah Cummings, United States Representative, to Heather Bresch, CEO of Mylan, available at <a href="https://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing">https://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing</a>.

- (8) The identity of company official(s) responsible for setting the prices of these drugs over the above time period.
- 207. Mylan's letter provided that the requested information and documents be turned in to congressional offices by October 23, 2014. Defendants Actavis, Heritage, Sun, and West-Ward were requested to provide substantially similar information with regard to Doxycycline.
- 208. On February 24, 2015, Senator Sanders and Representative Cummings sent a letter requesting that the Office of the Inspector General ("OIG") of the Department of Health and Human Services "examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs." The OIG responded to the request on April 13, 2015, advising it would examine pricing for the top 200 generic drugs to "determine the extent to which the quarterly [Average Manufacturer Pricing] exceeded the specified inflation factor."
- 209. In August 2016, the United States GAO issued its report finding "extraordinary price increases" on many generic pharmaceuticals including Doxycycline.<sup>70</sup>
  - 2. The DOJ launched a broad criminal investigation into anticompetitive conduct by generic drug manufacturers.
- 210. The DOJ opened a criminal investigation into collusion in the generic pharmaceutical industry on or about November 3, 2014. The DOJ also empaneled a grand jury in this District at about the same time.

<sup>&</sup>lt;sup>68</sup> Letter from Sen. Bernard Sanders & Rep. Elijah E. Cummings, U.S. Cong., to Inspector Gen. Daniel R. Levinson, Dep't of Health & Human Servs. (Feb. 24, 2015), *available at* <a href="http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file">http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file</a>.

<sup>&</sup>lt;sup>69</sup> Letter from Inspector Gen. Daniel R. Levinson, Dep't of Health & Human Servs., to Sen. Bernard Sanders (Apr. 13, 2015), *available at http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.* 

<sup>&</sup>lt;sup>70</sup> GAO Report to Congressional Requesters, *Generic Drugs Under Medicare* (Aug. 2016), *available at* http://www.gao.gov/assets/680/679055.pdf.

- 211. Initial reports suggest that, at the beginning, the DOJ's probe was focused on two generic drugs: digoxin and doxycycline. However, news reports, court filings, and other public statements have confirmed the sweeping nature of the DOJ's investigation. Reportedly, the DOJ believes price-fixing between makers of generic pharmaceuticals is widespread, and its investigation could become the next auto parts investigation, which is the DOJ's largest prosecution to date. According to sources cited by Bloomberg, the DOJ investigation already "spans more than a dozen companies and about two dozen drugs." As noted elsewhere herein, the DOJ's investigation has yielded criminal guilty pleas from Glazer and Malek of Heritage concerning "doxycycline hyclate."
- 212. **Actavis:** Actavis' parent Allergan plc disclosed in public filings that it received a subpoena from the DOJ, on June 25, 2015, "seeking information relating to the marketing and pricing of certain of the Company's generic products and communications with competitors about such products."<sup>73</sup>
- 213. **Mayne**: In its 2016 Annual Report, Mayne Pharma Ltd. disclosed that it was "one of numerous generic pharmaceutical companies to receive a subpoena from the Antitrust Division of the US Department of Justice [] in the last two years seeking information relating to

<sup>&</sup>lt;sup>71</sup> Joshua Sisco, *DoJ believes collusion over generic drug prices widespread—source*, POLICY AND REGULATORY REPORT (June 26, 2015), *available at* <a href="http://www.mergermarket.com/pdf/DoJ-Collusion-Generic-Drug-Prices-2015.pdf">http://www.mergermarket.com/pdf/DoJ-Collusion-Generic-Drug-Prices-2015.pdf</a>.

<sup>&</sup>lt;sup>72</sup> David McLaughlin and Caroline Chen, *U.S. Charges in Generic Drug Probe to be Filed by Year-End*, Bloomberg (Nov. 3, 2016), *available at* <a href="https://www.bloomberg.com/news/articles/2016-11-03/u-s-charges-in-generic-drug-probe-said-to-be-filed-by-year-end">https://www.bloomberg.com/news/articles/2016-11-03/u-s-charges-in-generic-drug-probe-said-to-be-filed-by-year-end</a>.

<sup>&</sup>lt;sup>73</sup> Allergan, SEC 2015 Form 10-K (Feb. 26, 2016), at 27, *available at* <a href="https://www.sec.gov/Archives/edgar/data/1578845/000156459016013478/agn-10k">https://www.sec.gov/Archives/edgar/data/1578845/000156459016013478/agn-10k</a> 20151231.htm.

marketing, pricing and sales of select generic drugs" and that it had also received a subpoena from the CTAG seeking similar information.<sup>74</sup>

- 214. **Mylan**: Mylan disclosed in a 2016 filing with the United States Securities and Exchange Commission (SEC) that it received a DOJ subpoena "seeking information relating to the marketing, pricing, and sale of our generic Doxycycline products and any communications with competitors about such products." Mylan received a similar subpoena from the CTAG, seeking "information relating to the marketing, pricing and sale of certain of the Company's generic products (including Doxycycline) and communications with competitors about such products."
- 215. Subsequently, on November 9, 2016, Mylan disclosed in its quarterly report that both it and "certain employees and senior management, received subpoenas from the DOJ seeking additional information relating to the marketing, pricing and sale of our generic Cidofovir, Glipizide-metformin, Propranolol and Verapamil products and any communications with competitors about such products." Significantly, Mylan disclosed that "[r]elated search warrants also were executed" in connection with DOJ's investigation.
- 216. **Par**: Par disclosed in an SEC Form 10-K for 2014 that it received a subpoena from the CTAG on August 6, 2014, requesting documents related to Digoxin and that it had

<sup>&</sup>lt;sup>74</sup> Mayne, 2016 Annual Report (Aug. 25, 2016), at 75, *available at* <a href="https://www.maynepharma.com/media/1788/2016-mayne-pharma-annual-report.pdf">https://www.maynepharma.com/media/1788/2016-mayne-pharma-annual-report.pdf</a>.

<sup>&</sup>lt;sup>75</sup> Mylan, SEC 2015 Form 10-K (Feb. 16, 2016), at 160, *available at* <a href="https://www.sec.gov/Archives/edgar/data/1623613/000162361316000046/myl10k">https://www.sec.gov/Archives/edgar/data/1623613/000162361316000046/myl10k</a> 20151231xdo <a href="c.htm">c.htm</a>.

<sup>&</sup>lt;sup>76</sup> *Id*.

<sup>&</sup>lt;sup>77</sup> Mylan SEC Form 10-Q (Nov. 9, 2016), at 58, *available at* <a href="https://www.sec.gov/Archives/edgar/data/1623613/000162361316000071/myl10q\_20160930xdoc.htm">https://www.sec.gov/Archives/edgar/data/1623613/000162361316000071/myl10q\_20160930xdoc.htm</a>.

<sup>&</sup>lt;sup>78</sup> *Id*.

completed its response on October 28, 2014.<sup>79</sup> Par subsequently received a DOJ subpoena on December 5, 2014, "requesting documents related to communications with competitors regarding [its] authorized generic version of Covis's Lanoxin® (Digoxin) oral tablets and [its] generic doxycycline products."<sup>80</sup> In December 2015, Endo Pharmaceuticals Inc. (Par's parent company) disclosed that it "received Interrogatories and Subpoena Duces Tecum from the [CTAG] requesting information regarding pricing of certain of its generic products, including doxycycline hyclate, amitriptyline hydrochloride, doxazosin mesylate, methotrexate sodium and oxybutynin chloride." Notably, at least doxycycline hyclate, doxazosin mesylate, and methotrexate sodium were manufactured by DAVA prior to Endo's acquisition of DAVA in August 2014.

- 217. **Sun**: Sun also received a grand jury subpoena as part of the DOJ's generics probe.<sup>81</sup> Reportedly, the DOJ asked Sun for documents related to employee and corporate records and communications with competitors.<sup>82</sup>
- 218. Defendants are not alone. Numerous other generic manufacturers have likewise received subpoenas in connection with the DOJ's and the State AGs' broad investigations into anticompetitive conduct in the generic drug industry. Additionally, some of these generic manufacturers have disclosed that search warrants have been executed or that certain employees have been separately subpoenaed as part of these ongoing probes.

<sup>&</sup>lt;sup>79</sup> Par Pharmaceuticals Companies, Inc., SEC 2014 Form 10-K (Mar. 12, 2015).

<sup>&</sup>lt;sup>80</sup> *Id*.

<sup>&</sup>lt;sup>81</sup> David McLaughlin and Caroline Chen, *U.S. Charges in Generic Drug Probe to be Filed by Year-End*, BLOOMBERG (Nov. 3, 2016), *available at* <a href="https://www.bloomberg.com/news/articles/2016-11-03/u-s-charges-in-generic-drug-probe-said-to-be-filed-by-year-end">https://www.bloomberg.com/news/articles/2016-11-03/u-s-charges-in-generic-drug-probe-said-to-be-filed-by-year-end</a>.

<sup>&</sup>lt;sup>82</sup> Zeba Siddiqui, *India's Sun Pharma Gets U.S. Subpoena Over Generic Drugs Pricing*, REUTERS (May 28, 2016), *available at* <a href="http://www.reuters.com/article/sun-pharm-usa-idUSL4N18P00X">http://www.reuters.com/article/sun-pharm-usa-idUSL4N18P00X</a>.

- 219. The fact that these companies received subpoenas from a federal grand jury is significant, as is reflected in Chapter 3 of the 2014 edition of the DOJ's Antitrust Division Manual. Section F.1 of that chapter notes that when deciding whether to request the initiation of a grand jury investigation "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution." The staff request needs to be approved by the relevant field chief and is then sent to the Antitrust Criminal Enforcement Division. He are Daag [Deputy Assistant Attorney General] for Operations, the Criminal Daag, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation." The investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred."
- 220. Receipt of federal grand jury subpoenas is an indication that antitrust offenses have occurred.
- 221. That a target has reportedly applied for leniency is also significant.<sup>87</sup> As the DOJ notes on its web site (<a href="http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program">http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program</a>):

<sup>&</sup>lt;sup>83</sup> DOJ, Antitrust Division Manual (5th ed. 2015) at III-82.

<sup>&</sup>lt;sup>84</sup> *Id*.

<sup>&</sup>lt;sup>85</sup> *Id.* at III-83.

<sup>&</sup>lt;sup>86</sup> *Id*.

<sup>&</sup>lt;sup>87</sup> Leah Nylen and Josh Sisco, *Generic drug investigation started small before ballooning to dozen companies*, MLEX (Nov. 4, 2016) ("While the Justice Department didn't have a whistleblower at the beginning of the investigation, it is understood that [in the summer of 2016]

## 5. Does a leniency applicant have to admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter?

Yes. The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or production volumes, before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will not qualify for leniency through the Leniency Program.

The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials." *Id*.

222. The DOJ's first charges were made on December 12, 2016, against Glazer and Malek with criminal counts related to collusion for doxycycline hyclate and glyburide. *See United States of America v. Jeffrey A. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa.); *United States of America v. Jason T. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa.). On January 9, 2017, both Glazer and Malek pleaded guilty to the charges. At their plea hearings, Glazer and Malek admitted, among other things, that their co-conspirators included "individuals that [Glazer] supervised at his company and those he reported to at his company's parent[.]" Sentencing for both Glazer and Malek was originally set for April 2017 but was later rescheduled to September 2017 as they continue to cooperate with the DOJ.

a company applied for leniency, which grants full immunity to the first company to come forward and admit to cartel violations."), *available at* http://www.mlex.com/GlobalAntitrust/DetailView.aspx?cid=841053&siteid=191&rdir=1.

223. The DOJ has intervened in MDL 2724 as well as numerous civil antitrust actions alleging price-fixing, bid rigging, and market and customer allocation of generic pharmaceuticals stating that these cases overlap with the DOJ's ongoing criminal investigation. For example, in a civil antitrust action related to the generic pharmaceutical propranolol, the DOJ intervened and requested a stay, stating that "the reason for the request for the stay is the government's ongoing criminal investigation and overlap of that investigation and this case," and that "the government's ongoing investigation is much broader than the [Glazer and Malek] informations that were unsealed."88 The DOJ filed a brief with the United States Judicial Panel on Multidistrict Litigation noting that, "The complaints in those civil cases – which typically allege that a group of generic pharmaceutical companies violated Section 1 of the Sherman Act by conspiring to fix prices and allocate customers for a particular drug – overlap significantly with aspects of the ongoing criminal investigation."89 As noted above, the DOJ also filed a motion for a stay of discovery in MDL 2724 stating that: "Evidence uncovered during the criminal investigation implicates other companies and individuals (including a significant number of the Defendants here) in collusion with respect to doxycycline hyclate, glyburide, and other drugs (including a significant number of the drugs at issue here)."90

## 224. The DOJ's Spring 2017 Division Update notes that:

Millions of Americans purchase generic prescription drugs every year and rely on generic pharmaceuticals as a more affordable alternative to brand name medicines. The Division's investigation into the generics market, however, has revealed that some

<sup>&</sup>lt;sup>88</sup> See Tr. of Hearing, In re: Propranolol Antitrust Litig., No. 16-cv-9901, ECF 112 (S.D.N.Y. Feb. 21, 2017).

<sup>&</sup>lt;sup>89</sup> See Memorandum of Amicus Curiae United States of America Concerning Consolidation, *In re: Generic Digoxin and Doxycycline Antitrust Litig.*, MDL No. 2724, ECF 284 (J.P.M.L. Mar. 10, 2017).

<sup>&</sup>lt;sup>90</sup> See Intervenor United States' Motion to Stay Discovery, *In re: Generic Pharm. Pricing Antitrust Litig.*, MDL No. 2724, ECF 279 (E.D. Pa. May 1, 2017).

- executives have sought to collude on prices and enrich themselves at the expense of American consumers.<sup>91</sup>
- 3. Led by the State of Connecticut, 45 state attorneys general launched their own investigation of antitrust violations in the generic drug industry.
- charges against two former executives of Heritage Pharmaceuticals. According to the State AGs' complaint, the information developed through its investigation (which is still ongoing) uncovered evidence of a broad, well-coordinated, and long-running series of schemes to fix prices and allocate markets for a number of generic pharmaceuticals in the United States.

  Although the State AGs' action currently focuses on doxycycline hyclate DR and glyburide, it alleges that the Plaintiff States have uncovered a wide-ranging series of conspiracies implicating numerous different generic pharmaceuticals and competitors. As reported by *The Connecticut Mirror*, the State AGs "suspected fraud on a broader, nearly unimaginable scale" and "new subpoenas are going out, and the investigation is growing beyond the companies named in the suit." CTAG George Jepsen has called evidence that has so far been obtained in the State AGs' investigation "mind-boggling."
- 226. CTAG George Jepsen confirmed the scope of the State AGs' action in the following press release:

My office has dedicated significant resources to this investigation for more than two years and has developed compelling evidence of collusion and anticompetitive conduct across many companies that

<sup>&</sup>lt;sup>91</sup> DOJ Website, Division Update Spring 2017 (Mar. 28, 2017), *available at* <a href="https://www.justice.gov/atr/division-operations/division-update-spring-2017/division-secures-individual-and-corporate-guilty-pleas-collusion-industries-where-products">https://www.justice.gov/atr/division-operations/division-update-spring-2017/division-secures-individual-and-corporate-guilty-pleas-collusion-industries-where-products</a>.

<sup>92</sup> Mark Pazniokas, *How a small-state AG's office plays in the big leagues*, The Connecticut Mirror (Jan. 27, 2017), *available at https://ctmirror.org/2017/01/27/how-a-small-state-ags-office-plays-in-the-big-leagues/*. *The Connecticut Mirror* further reported that the DOJ grand jury was convened in this District shortly after the CTAG issued its first subpoena. *Id.* 

manufacture and market generic drugs in the United States. . . . While the principal architect of the conspiracies addressed in this lawsuit was Heritage Pharmaceuticals, we have evidence of widespread participation in illegal conspiracies across the generic drug industry. Ultimately, it was consumers — and, indeed, our healthcare system as a whole — who paid for these actions through artificially high prices for generic drugs. We intend to pursue this and other enforcement actions aggressively, and look forward to working with our colleagues across the country to restore competition and integrity to this important market. <sup>94</sup>

- 227. In filings with the United States Judicial Panel on Multidistrict Litigation on May 16, 2017 and June 13, 2017, the State AGs reiterated that their ongoing investigation is broad in scope and goes beyond doxycycline hyclate DR and glyburide. The State AGs further stated that their doxycycline hyclate DR and glyburide action "encompass[es] illegal agreements including with regard to Doxy DR where prices remained constant (or remained higher than they would have been in a competitive market) as a result of customer or market allocation agreements designed specifically to avoid price erosion[.]" The State AGs also disclosed that they have entered into settlements with Glazer and Malek and that these settlements require Glazer and Malek's cooperation with the State AGs.
- 228. During a conference call on July 27, 2017, W. Joseph Nielsen, an assistant AG for the State of Connecticut, said "he expects future actions by the group of states investigating price-fixing and market allocation in the generic drug industry" including "more lawsuits against additional generic manufacturers for additional drugs [and] lawsuits against high-level

<sup>&</sup>lt;sup>94</sup> CTAG Website, Press Release, Connecticut Leads 20 State Coalition Filing Federal Antitrust Lawsuit against Heritage Pharmaceuticals, other Generic Drug Companies (Dec. 15, 2016), available at http://www.ct.gov/ag/cwp/view.asp?Q=588538&A=2341.

<sup>&</sup>lt;sup>95</sup> See Brief and Reply in Support of Plaintiff States' Motion to Vacate Conditional Transfer Order (CTO-3), *In re: Generic Pharm. Pricing Antitrust Litig.*, MDL No. 2724, ECF 321 & 334 (J.P.M.L. May 16, 2017 & June 13, 2017).

executives for their roles in the collusion."<sup>96</sup> Nielsen also stated that the States AGs realized very quickly that the generic drug industry is "set up structurally in a way that fosters and promotes collusion among generic competitors" and that the State AGs' investigation "has expanded greatly to the point where we are now looking at numerous drugs."

- 229. New York AG Eric T. Schneiderman also reported that the State AGs' Action "uncovered evidence of a broad, well-coordinated and long running series of conspiracies to fix prices and allocate markets for certain generic pharmaceuticals in the United States." <sup>97</sup>
- 230. The DOJ's and State AGs' investigations of alleged price-fixing and other unlawful conduct in the generic pharmaceutical industry are ongoing.

## VI. THE DOXYCYCLINE MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

- 231. Because Defendants' anticompetitive conduct constitutes a conspiracy to fix prices and engage in market and customer allocation, which is a *per se* violation of Section 1 of the Sherman Antitrust Act, Plaintiffs need not define a relevant market. However, there are features of the market relevant to this case that show both (i) that the market is susceptible to collusion and (ii) that the price increases were in fact the result of collusion and not the result of conscious parallelism.
  - 232. Factors showing that a market is susceptible to collusion include in this case:
    - (1) **High Level of Industry Concentration** A small number of competitors (Defendants) control a substantial market share for Doxycycline, as detailed above.

<sup>&</sup>lt;sup>96</sup> Can Calik, Future actions by state enforcers expected over generic drug collusion, Connecticut official says, MLEX (July 27, 2017), available at <a href="http://www.mlex.com/GlobalAntitrust/DetailView.aspx?cid=908454&siteid=191&rdir=1">http://www.mlex.com/GlobalAntitrust/DetailView.aspx?cid=908454&siteid=191&rdir=1</a>.

<sup>&</sup>lt;sup>97</sup> New York AG Website, Press Release, A.G. Schneiderman Files Federal Antitrust Lawsuit With 19 Other States Against Heritage Pharmaceuticals And Other Generic Drug Companies (Dec. 15, 2016), available at <a href="https://ag.ny.gov/press-release/ag-schneiderman-files-federal-antitrust-lawsuit-19-other-states-against-heritage">https://ag.ny.gov/press-release/ag-schneiderman-files-federal-antitrust-lawsuit-19-other-states-against-heritage</a>.

- (2) Sufficient Numbers to Drive Competition While the market for Doxycycline had a small enough number of competitors to foster collusion, the number of makers was large enough that given decades of experience with competitive generic pricing, and accepted models of how generic companies vigorously compete on price one would have expected prices to remain at historical levels near manufacturers' marginal cost levels or to decrease. With the number of generic competitors such as there were here, historical fact and accepted economics teaches that absent collusion prices would remain at competitive levels or continue to decline.
- (3) **High Barriers to Entry** The high costs of manufacture, intellectual property, development and testing requirements, and lengthy time delay, related to regulatory approval and oversight are among the barriers to entry in the generic drug market. Specifically, any potential new entrants would have to go through the lengthy ANDA-approval process before coming to market, a process which takes many months, if not years. By insulating against new entrants, these barriers to entry and others increase the market's susceptibility to a coordinated effort among the dominant players to maintain supracompetitive prices.
- (4) **High Inelasticity of Demand and Lack of Substitutes** For majority of patients that rely on it, Doxycycline is a necessity that must be purchased regardless of price hikes. While there are other antibiotics on the market, there are significant barriers to changing treatments, and patients and physicians are likely to prioritize medical considerations over price. This makes demand for Doxycycline highly inelastic.
- (5) Absence of Material Non-Conspiring Competitors —
  Defendants have maintained a substantial market share for
  Doxycycline throughout the Class Period despite their
  supracompetitive pricing. Thus, Defendants have market
  power in the market for Doxycycline, which enables them
  to increase prices or maintain artificially inflated prices
  without loss of market share or substantial revenue to nonconspirators.
- (6) Opportunities for Contact and Communication Among Competitors Defendants participate in the committees and events of the GPhA, HDMA, MMCAP, NACDS, ECRM, and other industry groups, which provide and

- promote opportunities to communicate. The grand jury subpoenas to Defendants targeting inter-Defendant communications, further supports the existence of communication lines between competitors with respect to, among other things, generic pricing.
- (7) **Size of Price Increases** The magnitude of the price increases involved in this case further differentiates them from parallel price increases. Companies seeking to test market increases need to take measured approaches. But here the increases are not 5% or even 10% jumps the increases are of far greater magnitude. A rational company would not implement such large increases unless certain that its ostensible competitors would follow.
- (8) Reimbursement of Generic Drugs This market, as with many generic markets, has institutional features that would inhibit non-collusive parallel price increases. The reimbursement for generic pharmaceuticals to retail pharmacies is limited by MAC pricing, which is based on the lowest acquisition cost for each generic pharmaceutical paid by retail pharmacies purchasing from a wholesaler for each of a pharmaceutical's generic equivalent versions. As a result, there is an enhanced incentive to compete on price embedded in the generic reimbursement system.
- 233. Through their market dominance, Defendants have been able to substantially foreclose the market to rival competition, thereby maintaining and enhancing market power and enabling Defendants to charge Plaintiffs and the proposed Class members inflated prices above competitive levels for Doxycycline through unlawful price collusion.

### VII. CLASS ACTION ALLEGATIONS

234. Pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), Plaintiffs bring this action on behalf of Class defined as:

All persons or entities that directly purchased generic doxycycline hyclate (regular release capsules (50 or 100 mg) or tablets (100 mg)) or delayed release tablets (75, 100, and 150 mg)) from one or more of the Defendants in the United States and its territories and possessions at any time during the period from November 2012 through the present (the "Class Period").

Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, judicial officers and their personnel, and all governmental entities.

- 235. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe that there are dozens of Class members, geographically dispersed throughout the United States, such that joinder of all Class members is impracticable. Further, the Class members are readily identifiable from information and records maintained by Defendants.
- 236. Plaintiffs' claims are typical of, and not antagonistic to, the claims of the other Class members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants.
- 237. Plaintiffs will fairly and adequately protect and represent the interests of the Class and Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.
- 238. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation.
- 239. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the Class. Thus, determining damages with respect to the Class as a whole is appropriate. The common applicability of the relevant facts to claims of Plaintiffs and the proposed class is inherent in Defendants' wrongful conduct, because the overcharge injuries incurred by Plaintiffs and each member of the proposed class arose from the same collusive conduct alleged herein.

- 240. The common legal and factual questions do not vary among Class members and may be determined without reference to individual circumstances, and include, but are not limited to, the following:
  - (a) Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby increase prices of Doxycycline in the United States;
  - (b) The duration and extent of the alleged contract, combination, or conspiracy between and among Defendants and their co-conspirators;
  - (c) Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;
  - (d) The effect of the contract, combination, or conspiracy on prices of Doxycycline in the United States during the Class Period;
  - (e) Whether Defendants' conduct caused supracompetitive prices for Doxycycline;
  - (f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiffs and other members of the Class; and
  - (g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.
- 241. Treatment as a class action is the superior method for the fair and efficient adjudication of this controversy, as it will permit numerous similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, avoiding unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding as a class action, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.
- 242. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

### VIII. ANTITRUST INJURY

- 243. During the Class Period, Plaintiffs and Class members directly purchased Doxycycline from Defendants. Because of the Defendants' anticompetitive conduct, Plaintiffs and Class members were forced to pay more for Doxycycline than they otherwise would have, and thus have suffered substantial overcharge damages at the hands of Defendants. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.
- 244. Defendants' unlawful conduct has successfully eliminated competition in the market, and Plaintiffs and Class members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such overcharge damages will be calculated after discovery and upon proof at trial.
- 245. Defendants, through their unlawful conduct alleged herein, reduced competition in the Doxycycline market, increased prices, reduced choice for purchasers, and caused antitrust injury to purchasers in the form of overcharges.
- 246. Because Defendants' anticompetitive conduct is ongoing, Plaintiffs and the Class continue to pay supracompetitive prices for Doxycycline through the present.

## IX. CLAIM FOR RELIEF - VIOLATION OF SECTION 1 OF THE SHERMAN ACT

- 247. Plaintiffs repeat and re-allege the foregoing as though fully set forth herein.
- 248. In violation of Section 1 of the Sherman Antitrust Act, Defendants entered agreements with one another concerning the pricing of Doxycycline in the United States. This conspiracy was *per se* unlawful price-fixing.
- 249. Each of the Defendants has committed at least one overt act to further the conspiracy alleged in this Complaint. Defendants' anticompetitive acts were intentional, were directed at the sales of Doxycycline in the United States, and had a substantial and foreseeable

effect on interstate commerce by raising and fixing Doxycycline prices throughout the United States.

- 250. The conspiracy had its intended effect, because Defendants have benefited—and continue to benefit—from their collusion and the elimination of competition, both of which artificially inflated prices of Doxycycline.
- 251. The contract, combination, or conspiracy had the following direct, substantial, and reasonably foreseeable effects upon commerce in the United States:
  - a. Prices charged to and paid by Plaintiffs for Doxycycline were artificially raised, fixed, maintained, or stabilized at supracompetitive levels;
  - b. Plaintiffs were deprived of the benefits of free, open, and unrestricted competition in the sale of Doxycycline in the United States market; and
  - c. Competition in establishing the prices paid for Doxycycline was unlawfully restrained, suppressed, or eliminated.
- 252. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and Class members have been injured in their business and property in that they have paid more for Doxycycline than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown and will be determined after discovery and upon proof at trial.
- 253. Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.
- 254. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

255. Defendants' unlawful conduct as alleged herein poses a significant and continuing threat of antitrust injury.

## X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and Class members pray for relief from this Court and request:

- A. Certification as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiffs as Class Representatives and their counsel of record as Class Counsel;
- B. Adjudication that the acts alleged herein constitute unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;
- C. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiffs and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;
- D. An award to Plaintiffs and Class members of pre-judgment and post-judgment interest at the highest legal rate provided by law from and after the date of service of the first-filed Complaint in this action;
- E. An award to Plaintiffs and Class members of the costs of this suit, including reasonable attorney fees; and
  - F. An award of any further relief as the Court deems just and proper.

## XI. JURY TRIAL DEMANDED

Plaintiffs hereby request a jury trial on all claims so triable.

Dated August 15, 2017

NASTLAW LLC

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## **CERTIFICATE OF SERVICE**

I hereby certify that on August 15, 2017, a copy of the Consolidated Direct Purchaser Class Action Complaint was manually filed under seal with the Clerk of the Court and served upon counsel of record via electronic mail.